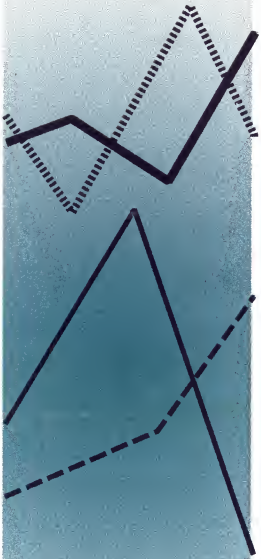


Impact of the Medicaid Drug Rebate Program

HCFA
Office of
Research and
Demonstrations

Extramural
Research
Report

Background

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) established a Medicaid drug rebate program. This program was enacted on November 5, 1990 and went into effect 54 days later on January 1, 1991. Specific provisions of the legislation included manufacturer rebates to Medicaid programs, general elimination of States' authority to use restrictive formularies, and some additional requirements for States' implementing prior authorization programs. At the end of 1994 the Medicaid drug rebate program had been in place for four years.

Evaluation of the Medicaid Drug Rebate Program

The overall purpose of this project was to assess the implementation and net impact of the Medicaid drug rebate legislation on access to, utilization of, and expenditures for prescribed drugs for the Medicaid population. The final report for this study addressed: the drug rebate program background and experience, a statement of the overall evaluation objectives, an overview of data sources and the evaluation framework, a descriptive analysis of aggregate trends, methods and findings of detailed State case studies, administrative impact case studies, and integration of study findings with a discussion of implications for policy and future research needs.

Project Objectives

The overall goal of this project was to assess the net impact of the Medicaid drug rebate legislation on access to, utilization of, and expenditures for drugs in the Medicaid population. The primary focus of the study was on change between 1990 (pre-OBRA 90) and 1992 (post-OBRA 90). Several specific research objectives were established to achieve this overall goal:

- Describe and analyze trends in Medicaid drug program expenditures before and after the OBRA 90 legislation and identify factors contributing to those trends.
- Document the amount of rebates accrued and collected and their impact on the total Medicaid drug expenditures.
- Evaluate the overall impact on Medicaid drug expenditures of changes in access to drugs due to discontinuation of restrictive formularies, implementation or modification of prior authorization programs, provision of six months open access after FDA approval of a drug product, and other State drug program policies and characteristics.
- Assess the impact of "open access" provisions (formulary discontinuation, six month mandatory coverage of products newly approved by FDA, and implementation or modification of prior authorization programs) on the number, mix, and cost of drugs used by Medicaid recipients.
- Document the administrative costs and rebate program implementation experiences of HCFA and the State Medicaid programs, including both start-up costs and continued operation costs.
- Determine the overall impact of the OBRA 90 legislation on net Medicaid drug expenditures, after accounting for the effect of rebates, changes in formulary and prior authorization programs, open access for newly approved drugs, and administrative costs.

Evaluation Overview and Limitations

The Medicaid drug rebate program is very complex and has been superimposed upon an already diverse environment of State Medicaid drug program policies. While it is not possible to enumerate all of the effects and repercussions of this national program on each State Medicaid program, the major effects can be isolated by identifying and controlling for some other known sources of variation. The impact of changes in the number and mix of Medicaid enrollees by

eligibility type, changes in drug restrictions such as formularies and prior authorization programs, and changes in manufacturers' drug prices can be determined. Some sources of variation can be described and quantified for nearly all States, but other sources require an extensive analysis of drug program expenditures at the individual prescription level and were, therefore, only practical for those States which had standardized MSIS data files that included prescribed medicines. The administrative impact assessment of the Medicaid drug rebate program required direct input from State and Federal Medicaid personnel through on-site and telephone interviews with selected States.

Three different sets of States were used for analysis in this project. First, the aggregate analysis of total Medicaid drug expenditures and rebates both at the national and State levels was performed using data derived from the HCFA Form 2082 reports by the States. One portion of this aggregate analysis examined a breakdown of expenditure and utilization data by basis of eligibility and medical assistance status for a subset of 27 States that had reported recipient and expenditure data broken down at this level for all years from 1988 to 1992. Aggregate rebate payments received were assessed using HCFA estimates drawn from HCFA Form 64 reports. In-depth State case studies of prescribed medicine use, cost and access were conducted on a selected set of nine States. One of these States (Kansas) had problems with enrollment data and was, therefore, left out of certain analyses. The third analytical set involved twelve States studied for the administrative impact of the rebate program.

Limitations of the study concern the databases available and the scope of the study. First, there were a number of limitations to the databases used in this study. For example, one of the original objectives of this study was assessment of changes in drug use rates as measured by days of therapy per recipient-year rather than number of prescriptions per recipient-year. This level of analysis was not possible, though, due to limitations of the Medicaid Statistical Information System (MSIS) other claims file which contains prescription claims. The quantity field for all prescription claims in this data set has been set to '1', meaning one prescription was provided. Prescription claims in most State databases, however, use the National Council for Prescription Drug Programs (NCPDP) uniform prescription claim form which, has the number of tablets, capsules, or milliliters in the quantity field allowing multiplication by a factor (e.g., units per day of therapy) to calculate the days of therapy provided by each prescription.

The Medicaid drug rebate program has had an impact on pharmaceutical manufacturers, other pharmaceutical purchasers, and many others. The scope of this study's objectives, however, was limited to assessment of the impact of the rebate program on State Medicaid agencies and the Health Care Financing Administration (HCFA). The study did not attempt to analyze the experience of pharmaceutical manufacturers with the drug rebate program.

This study limited its evaluation to examination of the expenditures for, and utilization of, outpatient prescribed medicines. Prescribed medicines used in inpatient settings were not included in this study. Also, the effect of the rebate program and related program changes (e.g., discontinuation of restrictive formularies and continuation or implementation of prior authorization procedures) on use of, and expenditures for, all other types of health care services and outcomes (e.g., hospitalizations, physician visits, long term care use, or patient outcomes) was not evaluated by this project.

Background of Medicaid Drug Rebate Program

Historically, Medicaid programs have covered outpatient prescription drugs, even though such coverage is defined as optional by the authorizing legislation. The national aggregate of State Medicaid expenditures for prescribed drugs nearly doubled in the five year period from 1985

to 1990, growing from $2.3 billion to $4.4 billion (*Pharmaceutical Benefits Under State Medical Assistance Programs*; Reston, VA: National Pharmaceutical Council, 1986 to 1991 annual reports).

Prescribed drug expenditures under Medicaid had been rising at an average annual rate of 13.9 percent in the five years prior to the rebate legislation. Many State governments face severe budgetary problems, in general, and with Medicaid, in particular. Medicaid is typically the single largest payer for outpatient prescriptions within each State, yet this government program traditionally does not have access to the discounts and rebates often obtained by certain other buyers, such as hospitals or HMOs.

The primary goals of the rebate program were to allow Medicaid programs to achieve savings in drug program expenditures and to increase Medicaid beneficiary access to drugs. Savings of $3.4 billion dollars over the five year period, 1991 to 1995, were expected (Pollard, Michael R. and John M. Coster, "I. Legislation. Savings for Medicaid Drug Spending," *Health Affairs*, vol.10, no.2, Summer 1991, pp. 196-206). Congress requested that HCFA prepare quarterly and annual reports on the rebate program and that other provisions (i.e., drug utilization review) be evaluated to determine the cost impact of the legislation.

Implementation of the rebate program was accomplished through a complex partnership between HCFA, State Medicaid agencies, and pharmaceutical manufacturers. The OBRA 90 drug rebate legislation included a number of specific operational components including:

- the minimum percentage component of the basic rebate;
- the best price component of the basic rebate;
- an inflation adjustment rebate;
- a general prohibition of restrictive formularies;
- open access to new drugs for 6 months after FDA approval (repealed after September 30, 1993); and
- conditions for operation of prior authorization programs.

The rebate amount due to the Medicaid program was dependent upon: (1) the drug product type (i.e., single source (SS), innovator multiple source (IMS), and non-innovator multiple source (NMS)); (2) the average manufacturer price (AMP) for a specific product; and (3) the manufacturer's best price for the same product. Each of the participating manufacturers reports the required pricing data on a quarterly basis to HCFA. HCFA uses this information to compute a unit rebate amount (URA). This URA, linked to a unique drug product NDC number, is provided to the States on a data tape each quarter.

Each State determines the utilization volume of each specific drug product (i.e., for each NDC number, which specifies a certain drug entity, dosage form, strength, package size and type, and manufacturer or labeler) based on Medicaid paid claims data for the quarter. The URA times the number of units utilized results in the amount of rebate due for a specific drug product. If the manufacturer disagrees with the utilization data, a disputed claim may result. Disputed claims may lead to delayed payments and additional administrative costs for both the States and the manufacturer due to generation of specialized reports or audits to estimate or verify the utilization of a specific drug product.

National Aggregate Analysis of Medicaid Drug Expenditures and Rebates

Medicaid Data Sources

Data for this overview has been drawn from three principal sources. First, State-specific and national aggregate data were drawn from the Health Care Financing Administration's (HCFA) Form 2082 and Form 64 reports. Second, additional Medicaid drug expenditure, enrollment, and pharmaceutical program data were extracted from the annual reports titled, *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA: National Pharmaceutical Council, annual reports from 1975 to 1994). A third reference, used primarily as a source of

information on Medicaid drug rebate trends, was the set of annual reports published by HCFA titled, *Report to Congress: Medicaid Drug Rebate Program* (Health Care Financing Administration, 1992, 1993, and 1995).

Medicaid Drug Expenditures and Rebates

Drug Expenditures. Drug and total medical expenditures for Medicaid increased about tenfold between 1975 and 1993 in current year dollars. Medicaid drug expenditures in 1975 totaled $815 million and by 1993 had reached nearly $8 billion based on HCFA Form 2082 data (Figure 1 and Table 1). Drug payments grew from 5.4 percent to 7.8 percent of total medical expenditures between 1982 and 1993. Drug payments represented a larger share of Medicaid total vendor payments in 1993 than did physician payments at 7.8 percent and 6.8 percent, respectively.

Recent growth in total medical payments and drug payments has been particularly strong. Total medical payments in 1993 increased 109 percent since the 1988 payment level and more than 56 percent since 1990. Drug payments before rebates in 1993 represented an even more dramatic increase with 1993 payments 142 percent greater than in 1988 and 80 percent over the 1990 payment level.

Medicaid drug expenditures grew from $4.4 billion in FY 1990, the year before the rebate program, to $5.4 billion in FY 1991 and $6.8 billion in FY 1992, not accounting for rebates. The annual drug expenditure growth rates were 22.8 percent and 25.1 percent, respectively, in 1991 and 1992. These growth rates appear quite dramatic in comparison to the 13.9 percent average annual growth rate experienced between 1985 and 1990.

Before drawing any conclusions about the source of this growth in drug expenditures, however, it is important to point out that these expenditure figures have not been adjusted for rebate amounts (either billed or collected), the substantial expansion in the number of persons qualifying for Medicaid, or the effect of open formularies. In addition to establishing the drug rebate program, the OBRA 90 legislation expanded the eligibility criteria for Medicaid.

Recipients. The number of drug recipients under Medicaid grew from 17.3 million in 1990 to 19.6 million in 1991 (a 13.3 percent increase) and to 22.1 million in 1992 (a 12.8 percent increase). Between 1990 and 1992, the average annual growth rate in number of drug recipients was 12.9 percent. In contrast, during the five years from 1985 to 1990 the average annual growth rate in drug recipients was only 4.5 percent

The number of persons eligible for Medicaid at any point in time is difficult to determine. The total number of persons receiving any type of medical assistance service during a given period can be used as a functional proxy for total eligibles. The number of total Medicaid recipients remained remarkably stable at 21 million to 23 million recipients per year during the period 1975 to 1988 (Figure 2). However, both total and drug recipients have expanded considerably in the last five years. Since 1988 the number of total Medicaid recipients has grown more than 42 percent, reaching 32.7 million recipients in 1993. The number of Medicaid drug recipients expanded slightly faster than total recipients, with the 23.9 million drug recipients in 1993 representing a 43 percent increase over the 15.3 million drug recipients in 1988 and a 29 percent increase over the 17.3 million drug recipients in 1990.

The expanded Medicaid population in the five-year period, 1988 to 1993, appears to be more likely to use prescribed medications than recipients previously enrolled. Drug recipients have grown as a percent of total medical assistance recipients. In 1988, 67 percent of total medical assistance recipients were drug recipients, and the percentage in 1993 grew to more than 73 percent.

Drug Expenditure per Recipient. Intensity indicators are not directly influenced by changes in the number of enrollees, because the focus is on expenditures or units of service per person. The intensity of drug expenditures per drug recipient has grown steadily over the past two decades. The drug expenditure per drug recipient was $57.58 per year in 1975, $128.97 in 1983, and $333.50 in 1993, representing an increase of nearly six-fold since 1975.

Drug use intensity is measured as prescriptions per drug recipient per year. During the last two decades this intensity measure has grown gradually. In 1975 the average Medicaid drug recipient used 12.4 prescriptions per year. By 1983, drug recipients were receiving 13.0 prescriptions per year, on average, and in 1993 they averaged 14.6 prescriptions annually.

Drug expenditures per drug recipient have been growing at a faster rate than the number of prescriptions per recipient, indicating that a major portion of the growth in drug expenditure intensity is coming from growth in payments per prescription rather than from the number of prescriptions used. The annual rate of change in drug expenditures per drug recipient in both current and constant dollars has routinely grown faster than the number of prescriptions per drug recipient per year.

The annual rate of change in drug expenditure intensity (drug expenditures per drug recipient per year) over the last decade has ranged from 8 percent to 12 percent increases. The drug use intensity had annual rates of change ranging from -3 percent to +3 percent over the last ten years. From 1988 to 1993 the drug use intensity for drug recipients has grown less than 1 percent. Increases in drug use intensity do not appear to be a major factor in the growth of prescription expenditures in recent years.

Drug Expenditures by Recipient Type. The drug expenditure levels in a Medicaid program can be influenced, not only by the growth in recipients, but also by changes in the mix of types of recipients. Certain types of Medicaid recipients utilize more prescription medications and health care services than others. A set of 27 States was found to have reported such a breakdown for every year from 1988 to 1992. These 27 States accounted for about 64 percent of national drug expenditures over this time period and were considered to be broadly representative. This analysis drew its data from the HCFA 2082 forms as reported in the annual editions of *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA: National Pharmaceutical Council, various years).

Drug recipients and expenditures were grouped into four categories: aged, disabled and blind, AFDC-adult, and AFDC-child. All persons classified as other or unclassified were treated as missing for purposes of this examination. The AFDC-child group was found to be the largest group by number of recipients (46.7 percent), but they accounted for the smallest proportion (11.4 percent) of drug expenditures (Figure 3). AFDC-adults also accounted for a larger percent of recipients than expenditures. In contrast, the aged and those who are disabled/blind consumed a disproportionate share of the expenditures when compared with their share among recipients. The disabled and blind were only one-fifth of the recipients while consuming nearly one-half (46.2 percent) of drug expenditures.

The elderly Medicaid recipients represented 13.8 percent of the recipients and 30.1 percent of the drug expenditures. Similarly, the elderly represent about 12 percent of the overall United States population and account for over 34 percent of the outpatient drug expenditures (Joseph Thomas III and Stephen W. Schondelmeyer, *Report to Congress, Manufacturers' Price and Pharmacists' Charges for Prescription Drugs Used by the Elderly*, Health Care Financing Administration, Washington, DC, June 1990).

The number of recipients in the AFDC-adult and AFDC-child groups has been growing especially with the OBRA 90 mandated expansions as previously discussed. Despite the growth in number of the AFDC population,

provision of drug therapy for these groups is relatively inexpensive compared to the cost of drug therapy for aged and disabled/blind recipients.

Not surprisingly the elderly and the disabled have a much higher annual drug expenditure rate per recipient than do the AFDC-adult or AFDC-child groups. In 1992 the average Medicaid elderly had drug expenditures of $721 as compared with only $205 for an AFDC-adult and $80 for an AFDC-child. (Figure 4). Drug expenditures per recipient increased steadily between 1988 and 1992 in all categories. For most recipient groups the expenditure rate has nearly doubled in the last five years. The aged had expenditures of $380 per person in 1988, which increased to $720 by 1992. Expenditures for AFDC children were $41 per year in 1988 and reached $80 by 1992. AFDC adults saw their expenditure level grow from $95 in 1988 to $205 in 1992.

Prescription and Drug Product Payments. Cost efficiency indicators are measures of expenditures or payments per unit of service. The primary efficiency factor for the Medicaid drug program is the expenditure per prescription. The average Medicaid payment per prescription in 1975 was $4.64. By 1983 the average prescription payment was $9.93, and it reached $22.85 in 1993 (Figure 5).

The average payment per prescription can be subdivided into two components: the drug product payment and the dispensing fee payment. The average payment for each of these components has grown in current year dollars. The dispensing fee payment grew from $2.18 in 1975 to $4.11 in 1993, less than a two-fold increase over this 18-year period. In contrast, the average drug product payment has grown from $2.46 per prescription in 1975 to $18.74 in 1993, more than a seven-fold growth in this period.

The average dispensing fee payment actually decreased in constant dollars (1993) from $84 in 1975 to $4.11 in 1993, representing a 30 percent decline in real dollar terms (Figure 6). At the same time, the average drug product payment grew in constant dollars (1993) from $5.69 in 1975 to $18.74 in 1993. This accounts for more than a three-fold growth of drug product payments in real dollar terms.

Impact of the Medicaid Drug Rebate Program

Each State bills manufacturers for rebates based on utilization data and the specified unit rebate amount (URA). The amount of the rebate is to be paid to the State within 38 days of the postmark date for the invoice. The amount of rebates collected by a State Medicaid program must be subtracted from the total drug expenditures in order to determine the net expenditures for the drug program. Most States and HCFA do not report drug program expenditures as an amount net of rebates. When drug expenditures are examined as an amount net of rebates, one gets a different perception of drug expenditure trends.

Rebate amounts that accrued to the Medicaid program in the first two calendar years (1991 and 1992) of operation totaled $1.35 billion (Figure 7 and Table 2). During the first two fiscal years (1991 and 1992) the drug rebate amounts accrued were 10.3 percent of the total Medicaid drug expenditures, $1.26 billion accrued in rebates compared to $12.2 billion spent on prescribed medicines (*Report to Congress: Medicaid Drug Rebate Program*, Health Care Financing Administration, 1992 and 1993).

In fiscal year 1991 the rebate program had just begun. Rebates were first invoiced and collected during the third CY quarter of 1991 (fourth FY quarter), totaling about $110 million. During FY 1992, States reported collecting around $900 million in rebates (Figure 7 and Table 2). Rebate collections for FY 1993 reached about $1.41 billion. These rebate payments resulted in a 4.6 percent reduction in FY 1991 drug expenditures,

a 13.0 percent reduction in FY 1992 drug expenditures, and a 17 percent reduction in FY 1993 drug expenditures.

The impact of the rebate payments on Medicaid drug expenditure trends was reviewed in several ways. First, the drug expenditure per drug recipient was calculated after subtraction of rebate amounts collected. Although the total drug expenditure per drug recipient in 1993 was $333.50, this figure falls to $274.37 when collected rebates are subtracted. When adjusted for inflation (1993 constant dollars), the 1993 drug expenditure ($274.37) net of collected rebates per drug recipient was less than the 1990 drug expenditure per drug recipient ($282.11) experienced three years earlier, and nearly as low as the 1989 amount of $269.53. In other words, the rebate program has resulted in the drug expenditure per drug recipient, in constant dollars, leveling off over the first three years of the program.

The national aggregate change in drug expenditure per drug recipient between 1990 and 1992, when adjusted for rebates collected and general inflation, was a 2.9 percent decrease. When this same factor was examined on a State-by-State basis, 29 States had a lower drug expenditure per drug recipient in 1992 than in 1990 (Figure 8). Four States, in particular, had very large increases in drug expenditures per drug recipient (adjusted for rebates and inflation) between 1990 and 1992: West Virginia (33.5 percent), Kentucky (33.3 percent), Missouri (29.2 percent), and Massachusetts (18.4 percent) (Figure 8).

When rebates collected per prescription were subtracted from the average prescription payment, the average prescription payment in 1993 decreased from $22.85 to $18.80 in current dollars, a 17.7 percent reduction. This lower prescription payment amount net of collected rebates means that Medicaid was paying less for the average prescription in 1993 than it paid in 1991 ($18.80 versus $18.88). After adjusting for inflation (1993 constant dollars), the average prescription payment less rebates collected in FY 1993 ($18.80) was less than the average Medicaid prescription payment experienced four years earlier in 1989 ($19.08).

Rebates accrued were found to average around 11 percent to 14 percent of total Medicaid drug expenditures in 1992 and 1993. On the surface this proportion appears low, but total drug expenditures also include dispensing fee payments. These dispensing fee payments account for about 18 percent of the total drug expenditures. When dispensing fee payments are subtracted from total drug payments, the rebate amount rises to approximately 14 percent to 15 percent of the remaining drug product payment amount.

There are two general types of rebates and the amount of rebate due is a function of the type of drug product and the pricing practices of the manufacturer. The rebate types are: (1) the innovator (SS and IMS drug products) rebate which is (a) the larger of the *basic* rebate based on the minimum rebate percentage applicable for each quarter and year according to current legislative statute and the *best price* rebate which is difference between the AMP and the best price plus (b) an *additional (inflation adjustment)* rebate if AMP has risen faster than the CPI-u; and (2) the *non-innovator* rebate (NMS or generic drug products) which is based on the applicable minimum rebate percentage (11 percent). Drug products have been classified by the rebate legislation as single source (SS; i.e., still protected by a patent or another form of market exclusivity), innovator multiple source (IMS; an original marketers product which now has one or more competitors on the market), and non-innovator multiple source (NMS; non-originator versions of products which have lost their exclusivity). A brief analysis was performed at the national level using information from HCFA estimates to describe the relative proportion of the total rebate amount that is derived from each of the following: the minimum rebate, the best price provision, the additional (inflation adjustment) rebate, and the minimum generic (NMS) rebate.

In the first two years of the program, the *basic rebate* amount was the minimum amount due for SS and IMS drugs. A rebate amount of 12.5 percent of the average manufacturer price (AMP) was due for SS and IMS drug products. During CY 1992, the basic rebate component contributed between $78 and $106 million per quarter which represented about 39 percent of the total rebates accrued (Figure 9 and Table 3). According to rebate program revisions contained in the Veterans Health Care Act of 1992 the minimum basic rebate was increased to 15.7 percent of AMP beginning with the fourth quarter of CY 1992 and continuing during CY 1993. For CY 1994 the minimum rebate percentage was set at 15.4 percent, for CY 1995 it was set at 15.2 percent, and after 1995 the minimum percentage will be 15.1 percent.

A *best price* rebate is due beyond the basic minimum rebate if the manufacturer sells the product at a lower price to any customer not exempted by either the original legislation or the Veterans Health Care Act of 1992. The best price rebate is the difference between the AMP and the best price. During the first two years of the program (1991 and 1992), the best price rebate was capped at no more the 25 percent and 50 percent of the AMP, respectively. In the first year of the rebate program the best price contributed $30 to $50 million per quarter in accrued rebates, or 28 percent of all rebates accrued. The 1992 contribution of the best price component increased to about 34 percent of rebates accrued which was $60 to $80 million per quarter (Figure 9 and Table 3).

The *additional* rebate was added as a means to neutralize the manufacturer's steadily increasing prices to the Medicaid program. This rebate applies to the SS and IMS drug, but not the NMS drugs. The rebate is calculated by comparing the rate of general inflation (as measured by the CPI-u) since October of 1990 with the rate of change in each drug product over the same time period. An additional rebate amount is due above and beyond the basic and best price rebates for each percentage point, or fraction thereof, by which the drug product inflation exceeded the general inflation rate. That is, if a drug's price had increased 12 percent cumulatively since October 1990 and the general inflation rate over that period was 6 percent, the manufacturer would owe an additional rebate of 6 percent of the AMP. The additional rebate has grown over time from 21 percent of the total accrued rebate in 1991 to 26 percent of the rebate amount accrued in 1992 (Figure 9 and Table 3). This inflation-adjustment rebate contributed $69 million in the fourth quarter of CY 1992 and is expected to continuously grow as a proportion of the total rebate over time due to the cumulative nature of its inflation index.

The non-innovator, or generic, rebate is due on all non-originator drug products. These NMS drug products are not subject to the best price or additional (inflation adjustment) rebates. The non-innovator rebate is set by a fixed, minimum percentage equal to 10 percent of the AMP from 1991 to 1993 and 11 percent of the AMP after 1993. The NMS rebate has contributed $2 to $3 million of accrued rebate per quarter. This NMS rebate amount represents about 1 percent of the total accrued rebates, and this percentage has been shrinking over time (Figure 9 and Table 3).

The basic rebate for SS and IMS drugs was increased from 12.5 percent to 15.7 percent of AMP in the fourth quarter of 1992 by the Veterans Health Care Act of 1992, as described earlier. This growth in the minimum percentage for the basic rebate can be seen in the rebate amounts over time with a jump in the basic rebate amount (less best price contribution) in the fourth quarter of CY 1992 (Figure 9 and Table 3). The NMS rebate had a scheduled, one time increase from 10 percent to 11 percent at the end of 1993, but otherwise is not expected to change without legislative action. The contribution of the best price to the rebate amount will vary depending upon pharmaceutical manufacturers' pricing practices to favored customers which are not exempt from the best price calculation, as described earlier. The additional (inflation adjustment) rebate has been growing both in amount

and as a percentage of total rebates accrued. Since drug product prices have been growing to date, and are expected to continue growing, at or above the rate of general inflation (CPI-u, all items), the additional rebate should continue to grow in importance as a part of the total rebate amount.

Sources of Drug Expenditure Growth

The drug program expenditures (current dollars) increased 141.9 percent over the 5-year period (1988 to 1993) before accounting for rebates and 99.0 percent after adjustment for rebates accrued. When general inflation (21.9 percent) over this 5-year period is taken into account, the drug expenditures (1993 constant dollars) increased 98.5 percent before rebates and 63.3 percent after rebates.

The single largest factor contributing to the growth in drug expenditures between 1988 and 1993, before adjustments for inflation and rebates accrued, was payment amount per prescription for the drug product. This factor showed a 66.3 percent increase in current dollars and a 36.4 percent growth in constant (1993) dollars. Close behind in growth rate for this 5-year period was the expansion of eligibles which resulted in a 55.9 percent jump in drug recipients. The growth of drug recipients does not change with adjustment for inflation or rebates, leaving this factor as the single largest factor contributing to growth in drug expenditures after other factors have been adjusted. Drug use intensity (number of prescriptions per person per year) grew by only 0.4 percent between 1988 and 1993, and, like drug recipients, this factor is not affected by adjustments for rebates or inflation. With adjustments for rebates accrued and general inflation (21.9 percent over the 5-year period), the average prescription payment grew 4.3 percent while the drug product payment grew by 6.9 percent, and the dispensing fee payment decreased 4.3 percent (Figure 10).

The relative contribution of each factor leading to growth in Medicaid drug expenditures from 1988 to 1993 can be estimated by determining the expenditure expected from change in that factor while holding each of the other factors constant over the five year period. The growth in number of drug recipients appeared to be the single largest growth factor over the past five years. If no growth had occurred in the number of eligibles or recipients (i.e., if drug recipients had remained at 15.9 million rather than growing to 23.9 million) the estimated drug expenditures in 1993 would have been $5.1 billion instead of $8.0 billion (Figure 11). The general inflation rate for this five-year period was about 22 percent (CPI-U all items). After factoring in this general inflation component, the 1993 drug expenditure would have been $4.2 billion in 1988 constant dollars, if all other factors remained constant. Finally, the rebates accrued from 1991 to 1993 would have further reduced the 1993 net Medicaid drug expenditure to about $3.1 billion in 1988 constant dollars.

In summary, more than one-half of the growth in drug expenditures between 1988 and 1993 was attributable to recipient growth, about one-fifth was due to general inflation, and nearly one-fourth was due to payments made to pharmaceutical manufacturers, through community pharmacies, which were later recovered by the States in the form of rebate payments.

State Case Studies: Based on Detailed Claims Analysis

Objectives

The primary focus of these case studies was on changes in drug expenditures before and after the Medicaid rebate program was implemented. The case studies used individual-level claims data to compare drug expenditures for two six-month observation periods before and after implementation of the rebate program in January 1991. The time periods chosen were from January through June in 1990 and the comparable period in 1992. Two States, however, had

usable data for only one quarter in 1990. The post-rebate period was chosen to be one year after the rebate program initiation to allow for HCFA and the States to work through implementation issues.

The State case studies employed detailed person-level enrollment and utilization data and NDC-level drug product data. This enabled analysis of drug expenditures by therapeutic category, drug patent status, and Medicaid recipient eligibility type for each case study State.

The overall goal of this series of State-level case studies was to determine the relative contribution of various sources to changes in drug expenditures experienced after implementation of the Medicaid drug rebate program. Several specific objectives were addressed for each case study State. These objectives were:

- Determine the change in drug claims and expenditures from 1990 to 1992.
- Identify changes in the number and mix of enrollees from 1990 to 1992.
- Examine changes in drug expenditures by drug patent status and therapeutic category from 1990 to 1992.
- Estimate changes in drug expenditures after adjusting for enrollment growth and shifts in enrollee use rate from 1990 to 1992.
- Calculate drug expenditures net of rebates in 1992 and the change from 1990 drug expenditures.
- Assess changes in drug benefit restrictiveness due to formularies and prior authorization from 1990 to 1992.
- Perform a decomposition analysis to determine the relative role of various factors contributing to change in Medicaid drug expenditures.

Methodology

From the list of States participating in HCFA's MSIS claims data system, several criteria were used to isolate the States for case study. These criteria included: (1) exclusion of States with significant capitated plan enrollment, especially if prescribed drug claims data was likely to be incomplete; (2) exclusion of States where there were a large number of State-specific drug codes that could not be matched to NDC codes; (3) exclusion of States with an unusually large proportion of adjustments to drug claims; and (4) inclusion of only those States with evidence of "believable" numbers of unique NDC codes for paid claims. Next, consideration was given to the size and policy differences among States. Both large and small States were desired in the study set to determine if the size of a State differentially affected its change in expenditures. Also, States with different policy environments were sought in the study set. In particular, it was considered desirable to have States with differing levels of restrictions to drugs before and after OBRA 90. Subsequent to OBRA 90, some States became much less restrictive in the use of prescribed drug products (e.g., Missouri, which had a restrictive formulary until 1991), while other States maintained similar levels of restriction or became more restrictive (e.g., Arkansas imposed global limits on the number of prescriptions per recipient per month). Nine States were selected for the in-depth case study analysis: Arkansas, Georgia, Indiana, Iowa, Kansas, Missouri, New Hampshire, Utah, and Washington.

"Date of service" claims files and matching enrollment files for the study periods were developed. MSIS claims files are "date of payment" files, which means that they include claims paid in a certain time period regardless of when the service was provided. The claims files developed for this study by Mathematica Policy Research included claims for prescribed drugs which were dispensed during the study period. The enrollment files include only those individuals enrolled during any one or more of the study months.

The unit of analysis for these State-level MSIS case studies was the drug product line item or the NDC level. Each NDC represents a unique drug entity, dosage form, strength, package size, and

manufacturer or labeler. All SS and IMS drugs were studied at the NDC level. NMS, or generic drugs, were aggregated so that all generically equivalent drug products, regardless of the manufacturer or labeler, were included in the same generic group. There are two major reasons why the NDC was chosen as the basic unit of analysis. First, Medicaid rebate utilization and unit rebate amounts are determined at the NDC level. Second, use of the NDC-level permits merging information about the drug (e.g., therapeutic class) to the expenditure and utilization files.

Change in Drug Expenditures Before and After the Rebate Program

The total drug expenditures for case study State Medicaid programs between 1990 and 1992 grew by amounts ranging from 21 percent in Arkansas to 115 percent in Missouri. The influence of enrollment increases can be minimized by examining the expenditure per enrollee per year. Although Missouri had the lowest annualized expenditure per enrollee per year in 1990 ($192), this amount had grown to $338 by 1992. This 76 percent increase was the highest of any study State. Georgia actually experienced a decrease in expenditure per enrollee and Arkansas held essentially even between 1990 and 1992. Missouri's dramatic increase in drug expenditures after OBRA 90 was associated with a substantial decrease in pharmacy benefit restrictions, especially elimination of a fairly restrictive formulary and discontinuation of a monthly limit on prescriptions per recipient. In contrast, Georgia and Arkansas instituted new restrictions after OBRA 90 including monthly prescription limits and addition of a number of drugs to their prior authorization programs.

The amount of change in drug expenditures after rebates varied widely across States, while the rebate amount as a percentage of drug expenditures was relatively stable. This observation would suggest that the amount of variation in expenditure increases is independent of the rebate amount. Drug expenditures in 1990 were compared with 1992 drug expenditures, with 1992 drug expenditures minus rebates, and with 1992 expenditures minus rebates and adjustment for changes in enrollment. After adjusting for rebates and enrollment growth, seven of the eight usable case study States had less than a 7 percent increase in expenditures over the two year period. For these seven States, this increase is equal to, or less than, the general rate of inflation.

A central question raised by the elimination of restrictive formularies, as mandated by OBRA 90, is how much any induced changes in utilization offset the benefits of rebate payments. This question is complicated by the numerous other changes driving shifts in utilization patterns. These other changes include: (1) changes in the size and composition of Medicaid enrollment, (2) underlying trends in the introduction of new drugs, (3) shifts in other State regulations such as the imposition, or removal, of monthly prescription limits, and (4) creation of new NDCs that reflect duplicate listings by the same manufacturer and identical versions of existing products with different prices. Untangling all of these possible factors within the resources available to this project was impossible, but a measure of differences among States was constructed to indicate the degree to which change in utilization and expenditures were offset by the benefits of rebate payments.

One effectiveness measure that can be calculated to assess the impact of the rebate program is the ratio of rebate payments accrued divided by the additional dollars of drug expenditures from changes in utilization. Both figures (rebates and expenditures) were adjusted to remove the effect of the often dramatic changes in enrollment, by multiplying expenditures per enrollee in 1992 times 1990 enrollment in each of four enrollment categories. A ratio above 1.0 indicates that the State received more rebate payments than it spent in additional dollars because of changes in utilization. The first ratio

(Table 4, Line II.a.) considers expenditures from all additional utilization; the second ratio (Table 4, Line II.b.) assumes that most, if not all, of the new NDCs (truly new drugs) would have been covered under the pre-1991 formularies and were therefore excluded from this indicator of induced changes in utilization. If the full amount of change in utilization is considered, all States except Missouri gained from the rebate program. Four of the States had modest gains — between 47 and 93 cents per dollar of additional rebates beyond the expenditures generated by changes in utilization patterns (Table 4 and Figure 12). Arkansas and Georgia did remarkably well under the rebate program, but also instituted substantial increases in drug benefit restrictions in the post-OBRA 90 period. The monthly restrictions on number of prescriptions per recipient and the prior authorization programs apparently have had a major impact in curtailing utilization in these States. In contrast to the increased restrictiveness of these two States, Missouri's essential deregulation of the pharmacy benefit produced a sharply differing net increase concurrent with implementation of the drug rebate program and other OBRA 90 provisions.

A much closer analysis NDC by NDC would be required to investigate the degree to which changes in regulatory status correlate with changes in utilization. Moreover, the results are quite sensitive to the assumptions made about the impact of enrollment changes on expenditures.

Decomposition of Factors Contributing to Drug Expenditure Changes

Changes in total prescribed drug expenditures are dependent on a number of factors. The detailed claims data were used to calculate independently the change due to each of the following: drug expenditures net of rebates, drug product prices (Laspeyre's Index), changes in number of users per 1,000 enrollees, changes in numbers of prescriptions per user (intensity), and enrollment changes. This decomposition of relative composition was performed only on the set of drug products (NDCs) used in both years (i.e., 1990 and 1992).

The independent contributions of these factors in each State, as well as the aggregate changes in total drug expenditures and drug expenditures net of rebates have been calculated. The lowest aggregate increase in expenditures before rebates were considered was observed in Arkansas (9.4 percent) and the greatest increase in Missouri (72.3 percent) (Table 5 and Table 6). Net of rebates, Arkansas had a decline in expenditures, while other States displayed modest increases ranging from 1 percent (Georgia) to 36 percent (Missouri). Examining the components of the Arkansas experience indicates that a decline in number of users per 1,000 enrollees contributed greatly to the expenditure change; in fact, total expenditures rose at a lower rate than total enrollment for Arkansas between the 1990 and 1992 study periods of those drugs used during both periods.

Drug product price indexes independently contributed from 11.3 percent to 21.4 percent increases in drug expenditures, among the eight States examined. These price indexes were computed before considering the effect of rebates on lowering effective prices. There appears to be a good degree of consistency from State to State in drug product price increases. Given that these figures were determined by weighting each NDC's utilization, the differences in drug product mix will contribute to some differences in the price index values from State to State. Seven of the eight States examined displayed price index changes ranging from 11 percent to 16 percent, over the two-year period examined.

The pattern revealed by the decomposition analysis is relatively clear. Enrollment effects were substantial in each of the States examined, with some variation in the magnitude of the effect but all States had in excess of a 10 percent aggregate rise. Number of prescriptions per user had a relatively insignificant effect, except in Missouri, with less than 5 percent change up or down over the two years in all other States.

Drug product prices (weighted by NDC use and expressed as an index) rose in all States, but are likely to have been ameliorated by the effect of rebates not taken into account here with respect to effect on drug product prices. A few States (Missouri, Arkansas, and Georgia) displayed more marked changes than others in the number of prescribed drug users per 1,000 enrolled, which is most likely due to changes in the types of restrictions (formularies removed, prior authorization expanded or imposed, and monthly prescription limits imposed or removed).

Change in Drug Expenditure by Therapeutic Category

One basis for grouping drugs is by therapeutic category. A hybrid therapeutic category coding scheme with 48 categories was developed for this project using therapeutic coding schemes resident within the First DataBank's Master Drug Data File. The percentage of total drug expenditures consumed by each therapeutic category was calculated. Expenditure patterns for Arkansas and Missouri were examined to illustrate expenditure differences across therapeutic categories. The H2 anti-ulcer drugs were the largest category in both States and accounted for more than 10 percent of expenditures in 1992. Calcium channel blockers were ranked second in expenditures by therapeutic class in both States.

A second set of figures by therapeutic categories displays the percentage change in drug expenditures between 1990 and 1992. The first striking observation is that certain categories in Missouri increased by as much as 400 percent to 900 percent. In general, these categories included drugs that had been restricted by the formulary prior to OBRA 90 and which were now openly available to Medicaid recipients. More than one-half (28 of 48) of the therapeutic categories in Missouri doubled in drug expenditures, and all therapeutic categories had an increase in drug expenditures in 1992 over 1990. In contrast, Arkansas actually had a decrease in expenditures for about one-fourth of the therapeutic categories.

When the change in drug expenditures was adjusted by subtracting rebates, Missouri still experienced an increase in expenditures for all but one therapeutic category (insulin). About one-half of the categories in Arkansas decreased in expenditure after accounting for rebates. A curious finding was that the therapeutic category (biologicals) with the greatest increase in Missouri was the category with the greatest decrease in Arkansas. In both States, however, biologicals were one of the smallest therapeutic categories by total drug expenditures.

The final perspective on therapeutic category by State was a look at the rebate amount as a percent of total expenditures. In both Missouri and Arkansas State-level case studies the top three categories included oral contraceptives, insulins, and estrogenic agents. Rebates ranged from 33 percent to 50 percent of the total drug expenditures for these therapeutic categories in Arkansas (Figure 13). The overall rebate amount calculated was 18 percent of expenditures for Arkansas and 21 percent for Missouri. Rebate amounts expressed as a percent of total drug expenditures appear to be fairly similar across States despite considerable variation in the drug program policies of the individual States.

Change in Number of NDCs and Growth of Repackagers

Even though the total number of prescription-related NDCs decreased between 1990 and 1992 from 64,671 to 58,930, there was a dramatic growth in the number of single source NDCs over the same period (3,578 to 6,073). This number of new single source NDCs appears to be far beyond what would be expected from new drug approvals by the FDA. Each year about 20 to 40 new drug entities are approved for marketing and several hundred new drug products including different strengths and dosage forms enter the market as single source products. The

jump of single source drug products by nearly 2,500 NDCs in two years seemed unusual. After examining the products accounting for this growth at the NDC level, a large proportion (1,254 of the 2,495 additional SS NDCs) of these products were found to be relabeled or repackaged single source products.

A repackaged single source product is one which still bears the originators trade name, so that the originator appears to have given at least implicit approval of the re-marketing of its product; otherwise, the drug company would have pursued trademark infringement against the re-labeler. The repackager applies for, and obtains, a new and separate NDC for its relabeled version of the originator drug product. At the same time the repackager can also set the list price and directly, or at least indirectly, the average wholesale price (AWP) for the product. Many repackaged products were found to have significantly higher AWPs per unit than the originator product, ranging from 5 percent increase to as much as a 500 percent increase. These same SS NDCs probably also have higher AMPs. By the end of 1994, single source repackaged products have grown to represent one-third of all SS NDCs. The implications of this repackaging practice on the rebate program warrant further exploration. That is, are these products being used in the Medicaid program? How does this practice affect the rebate amount? Is the higher price more than enough to offset the benefit of the rebate paid?

Access and Measures of Drug Restrictiveness

One of the trade-offs made in drafting the OBRA 90 legislation, which established the rebate program, was the prohibition of restrictive formularies. Some States responded to this change by using other approaches (i.e., prior authorization) to manage the pharmacy benefit program, while other States simply deregulated access to prescriptions under the Medicaid program. Drugs may be excluded from coverage by Medicaid, even after OBRA 90, based on a list of exclusions specified in the legislation. OBRA 90 contained other provisions, besides rebates, relevant to State decisions on prescribed drug coverage that were intended to expand recipient access to drug products:

- State formularies needed to include drugs covered by valid rebate agreements, if used for medically accepted purposes;
- Drugs newly approved by the FDA were to be covered for at least six months without formulary restriction; and
- Drugs could be subject to prior authorization, provided that a response needed to be made to requests for prior authorization within 24 hours and emergency supplies of 72-hours therapy could be dispensed, if necessary.

For this analysis a restrictiveness index was created to determine the relative change in access to drug products over time due to formularies, prior authorization, or other coverage rules. The Medicaid coverage restrictiveness index is a scale from 1 to 100. A value of 100 indicates the theoretical condition in which 100 percent of the marketed drug products are restricted or not covered. Conversely, a value of 1 indicates that virtually all of the marketed drug products are available without restriction.

For each of the case study States, the First DataBank Medicaid Drug File contained information on formulary status, coverage status, prior authorization, other coverage codes, and maximum allowable cost amounts for generic products. The 1992 coverage restrictiveness index was adjusted to account for NDCs not covered due to lack of a manufacturer rebate agreement with HCFA. The Medicaid coverage restrictiveness index method was applied to the First DataBank file for each of the case study States. For the 1990 period several States had virtually no restrictions; i.e., Indiana had a score of 3 and New Hampshire had a score of 2 (Figure 14 and Table 7). In contrast, other States had many restrictions such as a score of 67 for Missouri, meaning that nearly two-thirds (at the

NDC level) of the drug products were not reimbursed by the Missouri Medicaid program prior to OBRA 90. Georgia had a similarly restrictive formulary with a coverage restrictiveness score of 64 in 1990. A State whose restrictiveness index decreases from a higher number to a lower number is a State where the access to prescribed drugs has become less restrictive, at least in terms of formulary restrictions. The coverage restrictiveness index in Missouri, for example, changes from 67 (very restrictive) in 1990 to 9 (very unrestricted) in 1992. A change in the other direction was experienced by Indiana which had a coverage restrictiveness index score of 3 in 1990 and 6 in 1992 which means that access to drugs become slightly more restrictive.

Administrative Costs of the Rebate Program

The drug rebate program was an incremental policy change superimposed upon existing State drug benefit policies. As such, the manner in which the program was integrated into agencies varied, dependent upon State Medicaid program organizational characteristics. In this analysis the implementation experience of twelve selected States with the rebate program was examined. Difficulties experienced with the program and factors favorable for implementation were identified. Also, estimates of the cost of implementation and operation of the drug rebate program were developed.

Methodology

Twelve States were selected for interviews. These States ranged in Medicaid program size, ranked by total Medicaid claims expenditures for all services, from number 2 (California) to number 46 (Vermont), providing a good range in terms of total expenditures. The selection process was a non-random one, and thus, caution should be exercised in attempts to generalize the findings to all States. Three States were selected for site visits and interviews were conducted during April and May of 1994, and telephone interviews with the other nine States were conducted during July and August of 1994. Structured interview protocols were used in all cases. Medicaid program staff were also encouraged to raise any issues relevant to implementing and operating the program that were important but not addressed by the specific questions. Additionally, cost data collection forms were developed and delivered to each of the States participating in the telephone interviews, in order to facilitate the collection of cost data. Care was taken to include in the documentation of interviews only information provided by those interviewed, rather than subjective impressions of the interviewers. In most States, the needed information was provided by Medicaid outpatient drug benefit program managers. In a few States, this information was augmented as needed by discussions with State Medicaid directors, financial managers, or contractual claims processors.

Rebate Program Implementation

As mentioned earlier, HCFA had only 54 days from enactment to the effective date for beginning the Medicaid drug rebate program and other OBRA 90 provisions. A HCFA rebate program telephone hotline was developed early during implementation, so that manufacturers, State rebate program directors, and others concerned could have ready access to HCFA personnel. The hotline was reported to have received a massive number of calls in the early stages of the program, since all participants were attempting to decipher the program and plan their portions of it at once. The use of the hotline, in conjunction with the advisory groups formed to provide consultation to HCFA, facilitated the communications process as the program developed. HCFA also used a selected group of State pharmaceutical program directors to form a technical advisory group (TAG), convened by conference calls, that could identify and address implementation problems.

One of the most frequently mentioned problems by the States was reconciling rebate amounts due with manufacturers. Differences in utilization estimates can occur for a variety of reasons including: (1) claims billing problems with pharmacies that are not detected by system edits, including differing use of unit types by pharmacies; (2) manufacturers' attempts to verify Medicaid utilization data using non-Medicaid specific proprietary data sources; and (3) drug coding errors made as prescriptions are filled. A manufacturer would typically attempt to verify Medicaid utilization figures using their own records on product sales to wholesalers in a State, or according to surveys of pharmacies carried out by third parties, but that were not comprehensive in scope. Some of the problems mentioned with such data sources were:

- Pharmacies may purchase drugs from out-of-State wholesalers or have their own out-of-State warehouses, then sell prescriptions to in-State Medicaid recipients;
- Manufacturers who use their in-State wholesaler data multiplied by the aggregate Medicaid market share in a State would not adequately reflect the variation for specific product market shares;
- Nursing homes may purchase prescription drugs from out-of-State pharmacies; and
- Surveys of pharmacies conducted by proprietary sources typically do not include pharmacies that specialize in nursing home prescriptions, and so may underestimate these sales.

State Resources and Staffing Related to the Rebate Program

This analysis sought to determine the effects of the rebate program and related aspects of OBRA 90 on administration of prescription drug benefits, including effects on staffing patterns and organizational structures. Before OBRA 90, drug benefit policies were administered in most States by a few staff members. In most States, the person in charge of the drug benefit program was a pharmacist, who may or may not have had assistants. Where prior authorization programs were present, these were generally administered by additional State personnel or by contract personnel, usually with pharmacy backgrounds.

Of the nine States interviewed by telephone, one reported an increase in Medicaid prescription drug program staff by three full-time persons after OBRA 90. These three staff members were originally hired in order to decrease prior authorization response time to the specified limit of 24 hours. After the Medicaid agency later decided to operate the prior authorization program by contractual arrangement, the State staff were retained for the drug unit and re-assigned to tracking rebates received. One other State reported substantially increasing its contract staff available to the Medicaid prescription drug program in order to administer rebates. The seven remaining States interviewed by telephone made few drug program staffing changes as a result of OBRA 90, beyond minimal changes to fiscal agent contracts in order to develop needed utilization data and invoices. States interviewed during site visits reported hiring freezes; and they described in depth how difficult it was to obtain approval to hire staff through the Medicaid program. To have increased rebate program staff would have been perceived as "expanding State government." Developing outside contracts to handle new functions was reported as far easier for State administrators in terms of obtaining needed approval, because the contract services were considered qualitatively different from hiring actual employees. The cost of contractual services did not appear necessarily lower than that for State employees, however.

State Policy Issues for the Rebate Program

State Medicaid program administrators were faced with four main policy issues associated with the implementation of the drug rebate program. First, they needed to restructure drug benefit programs to be in compliance with OBRA 90 mandates and communicate changes

to practitioners. Second, they had to modify information systems to collect, assemble, and report the data needed to compute and send invoices on rebates. Third, they developed ways to work with manufacturers in order to collect rebates. Fourth, they needed to address their State administrative requirements, including development of rules and regulations on the program. Each of these major policy issues and the strategies adopted by States to implement them is described below.

Six of the twelve States interviewed for the administrative impact analyses reported having had restrictive formularies in 1990. These States were: Arkansas, California, Georgia, Kansas, Missouri, and Ohio. One of the research questions to be considered is: To what extent were existing formularies converted to extensive or expanded prior authorization programs? Also, what effect did any changes in drug coverage (or access) have on utilization and expenditures? The States in this study were reviewed for the pre- and post-OBRA periods to determine the presence of restrictive formularies, status and extensiveness of prior authorization programs, and other restrictions on prescription drug benefits. Interviews with these States covered prior authorization programs in depth, including any changes made to those programs after OBRA 90. Prior authorization (PA) programs were apparently not greatly expanded due to OBRA 90, even when formularies were discontinued. The only State interviewed (Iowa) that reported expanding its prior authorization program substantially had no formulary prior to the legislation, and this expansion was part of overall cost containment efforts by the State Medicaid program. Another State, California, had made substantial modifications to its formulary and developed an extensive prior authorization program at about the same time as the rebate program was implemented, but reported in its interview that these changes were made in 1990 prior to OBRA 90 enactment.

The degree of restructuring needed for drug benefit programs depended upon each State's coverage policies prior to OBRA 90 and how similar these were to features allowed under the legislation. For many States, the OBRA 90 mandates provided few changes, but in other States the mandates required extensive changes. While States had developed their coverage policies, including formularies and prior authorization programs, over a period of many years, the OBRA 90 legislation required them to adopt new policies in a matter of months. Communicating changes in policies to physicians and pharmacists in the State was not a minor task. The potential existed for some Medicaid programs and providers to be confused by the changes in policy, leaving them uncertain as to which drugs could be covered under the program. Ideally, the phase-in schedule for the program would have allowed for the coverage changes to be completed and then communicated to providers over a period of months. The actual schedule required States to make many coverage changes retroactive for various periods of time.

The second major policy issue at the State Medicaid level centered on the development of administrative information systems for rebate data. While all of the State management information system programs had been designed to adjudicate claims and conduct some utilization review functions, these systems were modified to collect the data needed for OBRA 90. Modifications needed were not extensive in most cases. Manufacturers did not pay some invoices, but did not always provide explanations as to why they did so. States then needed to determine, through telephone calls and other means, which bills went unpaid and why. Additionally, some States faithfully computed the differential federal shares they owed from rebates for contraceptive products (90 percent federal share of payments and rebates) and other drug products, but other States may have overlooked this.

The third major policy issue related to the ways in which State staff and manufacturers worked together to resolve difficulties with the

program. A great deal of time and effort was devoted to communications, including phone calls and letters, between Medicaid administrators and pharmaceutical manufacturers, trying to clarify amounts of products utilized and invoiced. In some cases, State staff considered manufacturers to be helpful in terms of resolving questions, while in other cases, those interviewed felt that some manufacturers purposely obfuscated the issues in order to delay progress. This issue, involving the development of methods for effectively communicating accurate information both to manufacturers whose products have been used, and back again to the Medicaid agency that is owed the rebates, became a major implementation obstacle to efficiently operating the program.

The fourth major policy issue related to State agencies' needs to develop and disseminate State-level rules and regulations on the program. In some States, this was a relatively straightforward process, since the program had a federal mandate and could be automatically adopted. In other States, the regulatory structure of the State was such that public hearings had to be conducted, regulations needed to be published and could only be published according to a restrictive time schedule, and the like. Most States could not clarify their program requirements and regulations until guidance was received from HCFA on program characteristics. However, HCFA staff were in the midst of determining program requirements at the same point that States needed to be defining their rules, due to the short time schedule.

In general, the States reporting the fewest problems with operating the rebate program and with verifying drug utilization levels were the larger States which had more program staff and strong existing programs for auditing pharmacy claims and generating pharmacy-specific reports on utilization. Obstacles to implementation included: difficulties with claims processors in handling the program or in their ability to develop pharmacy and NDC-specific data on request; information systems needing substantial changes or improvements in order to create the type of data needed for claims verification; a lack of effective, standardized procedures for verifying data questioned by manufacturers; the need to relinquish formularies, a reluctance to develop intensive prior authorization programs, due mainly to cost considerations; and a very short time frame to develop the program and resolve issues.

State Administrative Costs for the Rebate Program

States included in the administrative impact interviews were asked to provide data on administrative costs of establishing and maintaining the drug rebate program. Only limited data on the costs of operating the rebate program have been collected by HCFA.

As drug benefit program directors had explained, most States had few resources available to operate the rebate program. This description was largely confirmed by the expenditure information submitted. Values are reported in aggregate for each of the three full years (1991, 1992, 1993) of rebate program operations, and in aggregate for the three-year average costs of each State. From 1991 to 1993, mean costs for the twelve States grew slightly from about $93,000 to about $123,000 per State, on average, with the median cost in each of the three years being between $50,000 and $90,000. The mean program cost was substantially higher than the median cost in each year for these States, due to one or two States having costs much higher than those of the other States.

The range of total program costs among States examined was substantial, with the year 1993 displaying the greatest variation between minimum ($49,600) and maximum ($628,400) costs per State. When each State's costs were averaged over the three-year periods, in order to compensate for year-to-year fluctuations, similar data patterns were observed. For the three-year

period (1991 to 1993), the study States reported an average of $106,500 in annual operations cost, with a median of $75,000 annually.

Using the three-year average costs, about 70 percent of the total rebate program costs, on average (for States able to break out costs by category) were allocated toward program staffing. Two States not breaking out costs by category had rebate programs operated nearly completely by outside contractors. The next greatest proportion of expenditures was devoted, on average, to computer systems programming costs. These costs represented about 18 percent of total expenditures. The remainder of expenses were devoted to computer purchases (about 6-7 percent on average), office operations (about 4-5 percent on average), and other miscellaneous cost items, such as furniture.

Aggregate data on rebate program collections for the States were examined. The gross rebate collection amounts appeared substantial. During 1991, the start-up year of the program, the mean rebates collected by the twelve States reporting were about $20 million, and the median was about $13 million. Two States did not collect any rebate revenues in 1991, due to slow start-up operations. Average rebates collected in dollar terms grew over time, as expected, since the prescription drug expenditures were also rising. Using the three-year averages developed for each State's rebate collections, the mean annual amount collected by these States in rebates was over $31 million, and the median over $20 million. States certainly are expected to vary in their rebate collections, since those with larger prescription drug expenditures also accrued greater rebate amounts.

Rebates collected by States as a percentage of total outpatient drug expenditures were examined. During 1991, the start-up year of the program, rebates collected by these twelve States constituted about 13 percent, on average, of their prescription drug claims expenditures. Rebate collection figures rose in 1992 and 1993 to 17.7 percent and 18.5 percent, respectively, of drug program expenditures on average for the States analyzed. The rebate amounts collected represent substantial discounts off the amounts expended for drugs used by the Medicaid population. Although comparable figures are not available on private sector prescription drug rebate or discount programs, several pharmaceutical manufacturers had voluntarily offered rebates to States of only approximately 10 percent of prices prior to OBRA 90.

Administrative costs of the rebate program were relatively low, as expressed in terms of rebates collected. During 1991 when only one quarter of rebate payments were collected by most States, the average cost of the program across States was only 0.5 percent of the amounts collected. Considering the three-year means for each State, program costs averaged 0.9 percent of amounts collected. From the administrative cost perspective, the program appeared efficient, given that less than 1 percent, on average, of the amounts collected were expended by State Medicaid programs for the program.

The cost of rebate program operations as a percentage of the prescription drug program expenditures, in aggregate, for these States was examined. The average program costs were 0.18 percent, 0.13 percent, and 0.11 percent of drug claims payments for 1991, 1992, and 1993, respectively. Some of the first and second years' costs of operating the rebate program were usually devoted to initial programming and other start-up efforts.

There appear to be economies of scale to operating the program in States with larger prescription drug claims cost, in comparison to States with lower prescription drug claims cost. The States among our analysis set that were lower in drug claims expenditures also had higher rebate operations costs, as a percentage of claims paid. For the six smallest States (in terms of Medicaid drug expenditures) in the analysis, the rebate program cost as a percentage of drug expenditures averaged 0.33 percent in 1991. For the five largest States, the comparable rebate cost statistic averaged 0.03 percent of total expenditures in 1991. This is consistent with the notion

that the rebate program appears to be predominantly a fixed-cost function, with the process of developing rebate reports and invoices taking similar amounts of resources regardless of the number of drug claims that must be aggregated. Also, each State generally deals with the same number of manufacturers to collect the amounts due.

One other observation warrants note. The States with the lowest collections of rebates, as a percentage of drug claims cost, tended to be the smallest States in this analysis set. Of the four States collecting 16 percent or less of total drug expenditures as rebates over the three-year period studied, three were among the lowest ranking five States in terms of total drug program expenditures. The program may have been overall more difficult for the smaller States to implement, since these States function with fewer resources and thus, have less flexibility when new program initiatives arise. Also, the smaller States may have lesser ability to substantially update claims data and information systems in comparison to larger States, contributing to difficulties with verifying utilization reports and defending rebate amounts invoiced.

Implications for Policy

Medicaid exists in a very complex policy and political environment. Many changes to Medicaid occur simultaneously making evaluation of individual changes difficult. To the extent that the rebate program helped to partially enable the financing of an expansion in Medicaid eligibility for certain populations including AFDC children and pregnant women, the rebate program appears to have succeeded. The number of Medicaid enrollees has certainly grown since 1990 and the trend line for drug program expenditures has been significantly lowered after accounting for rebates.

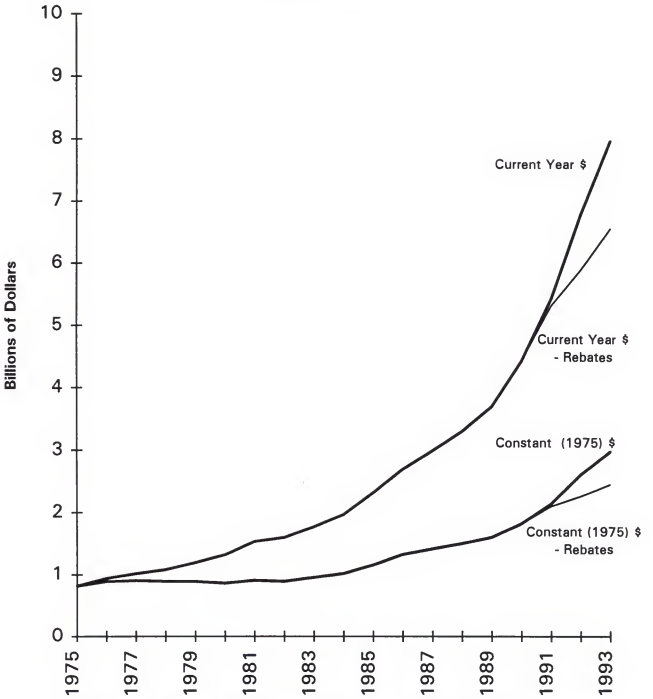
There are a number of policy implications raised by the drug rebate program and its current operation. First, both State and federal agencies continue to report their drug expenditures using the drug payments made without reflecting the receipt of rebate payments in the drug expenditure and total program statistics. This lack of transparency for rebate dollars can lead to a failure by policymakers to appreciate the substantial reduction in total drug expenditures achieved through the Medicaid drug rebate program.

Many State Medicaid programs have become dependent upon the revenue generated by the drug rebate program. Any major change in the rebate program would have a significant fiscal impact on State budgets. Some States place the drug rebate amounts directly into the general revenue fund, while others put the rebate funds directly back into the Medicaid program. A State would have to use additional general revenue dollars, cut eligibility, cut services, or cut payments to providers and producers to accommodate for a reduction in rebate payments. None of these changes is easy to accomplish in the current economic and policy environment.

As States consider alternative means for delivery of efficient and effective health care to the Medicaid population they must not overlook the role of the drug rebate program. In evaluating the cost of a managed care plan's coverage of prescription drugs as part of a comprehensive health benefit plan for Medicaid recipients, the role of rebate revenues should be considered. In most cases, when patients are shifted to managed care, the State Medicaid program does not directly receive rebates. While many managed care plans do receive rebates from drug companies, the value of these rebates to the State Medicaid program will not be realized unless they are passed on to the State as lower premiums or as separate payments based on utilization.

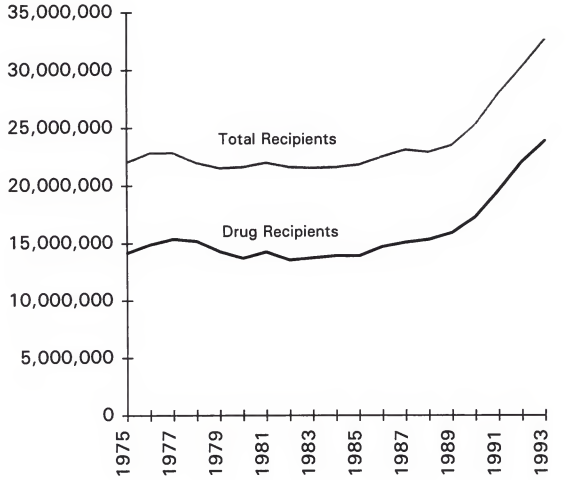
The Medicaid drug rebate program appears to have been a successful approach to managing the growth in drug expenditures over its first few years of operation. After accounting for other Medicaid program changes, the growth of Medicaid drug expenditures has slowed considerably and the net drug program expenditure for most States is substantially lower than would have been expected without the rebate program.

Figure 1.
Medicaid Drug Expenditures in Current and Constant (1975) Dollars: 1975 to 1993



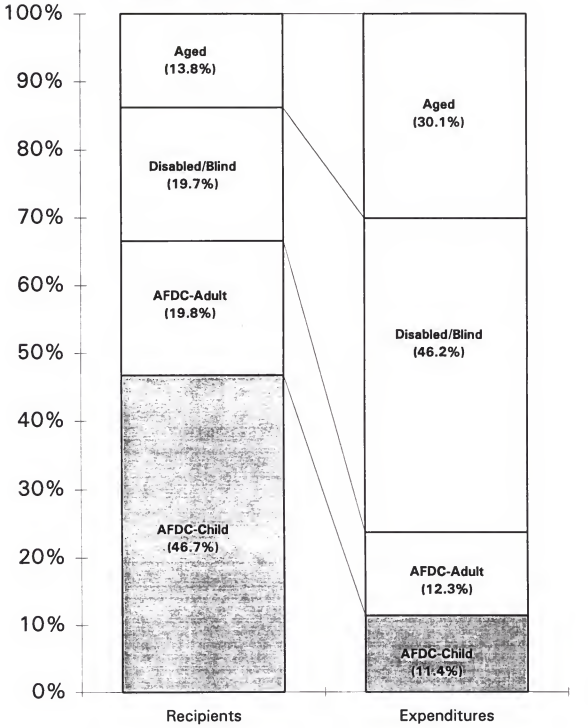
Source: P. Pine, et.al., *Health Care Financing Review*, 1992 Annual Suppl., pp.235-269; and *Pharmaceutical Benefits Under State Medical Assistance Programs*, National Pharmaceutical Council, 1975 to 1994.

Figure 2.
Total Medicaid and Drug Recipients:
1975 to 1993



SOURCE: P. Pine, et.al., *Health Care Financing Review, 1992 Annual Supplement*., pp.235-269; and *Pharmaceutical Benefits Under State Medical Assistance Programs*, National Pharmaceutical Council, 1975 to 1994.

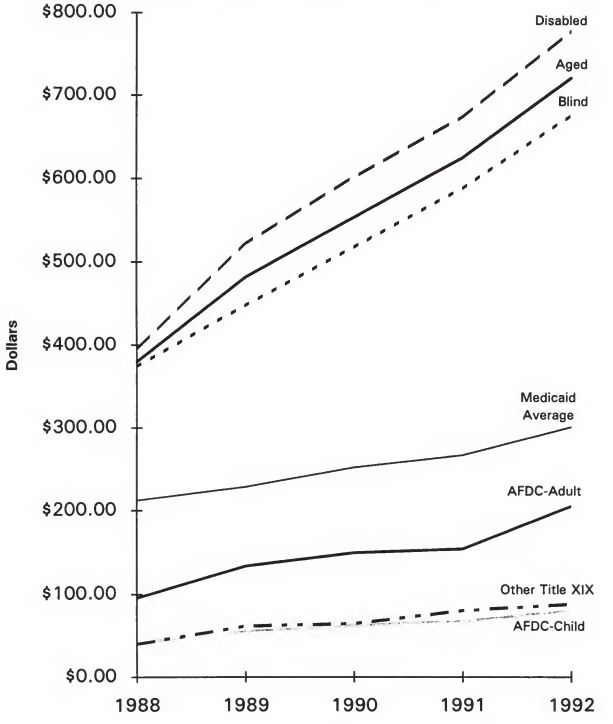
Figure 3.
Drug Expenditures and Recipients*: Distribution by Type of Recipient in 1992



*Based on data from 27 states reporting complete data in each year from 1988 to 1992.

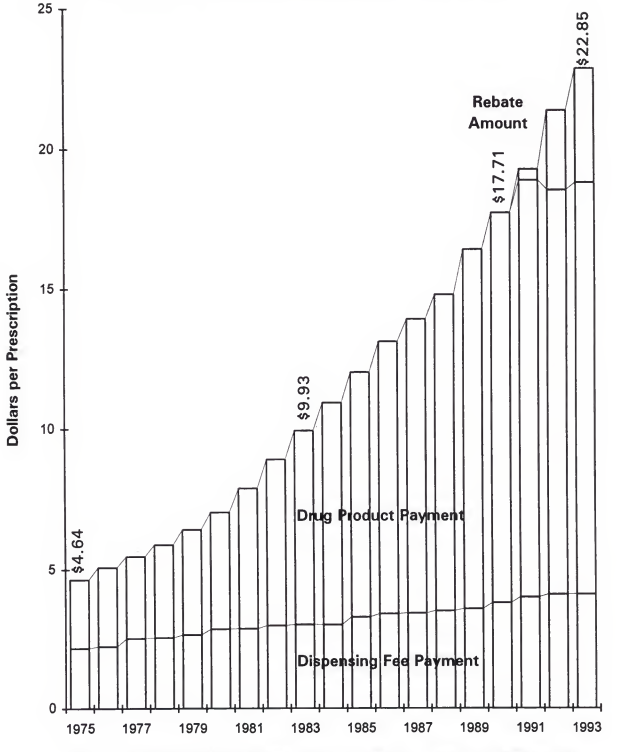
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA: National Pharmaceutical Council, annual reports, 1988 to 1993).

Figure 4.
Annual Drug Expenditure per Drug Recipient by Basis of Eligibility: 1988 to 1992



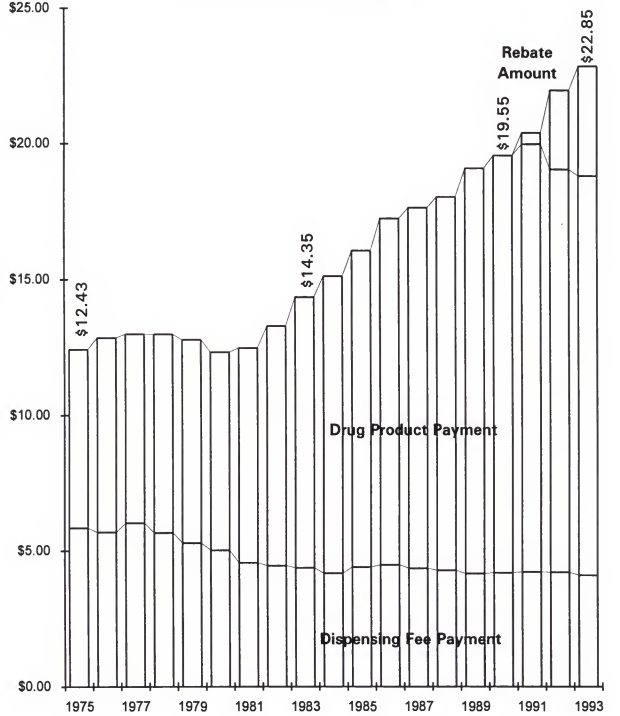
SOURCE: Based on 27 states with complete data by recipient type as found in *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA: National Pharmaceutical Council, 1988 to 1993).

Figure 5.
Medicaid Average Prescription Payment and Components: 1975 to 1993 in Current Dollars



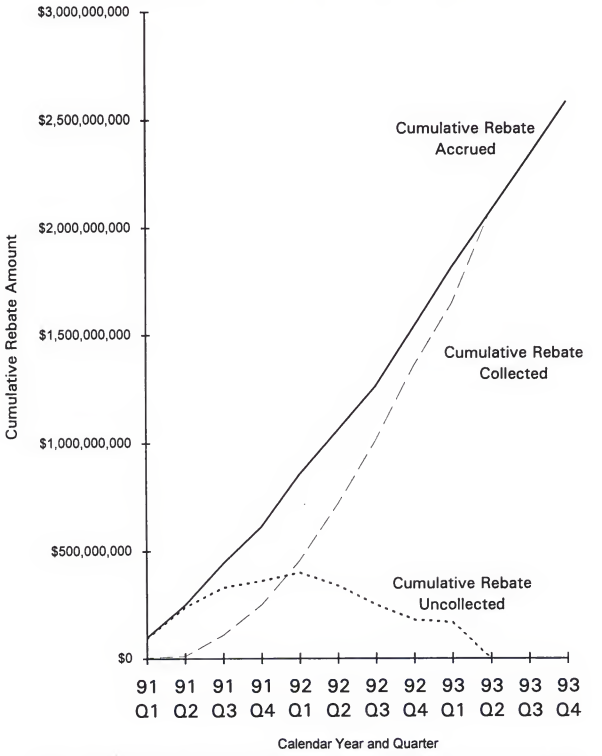
SOURCE: Compiled by the PRIME Institute University of Minnesota from data found in *Pharmaceutical Benefits UnderState Medical Assistance Programs*, National Pharmaceutical Council, 1975 to 1994.

Figure 6.
Medicaid Average Prescription Payment and Components: 1975 to 1993 in Constant 1993 Dollars



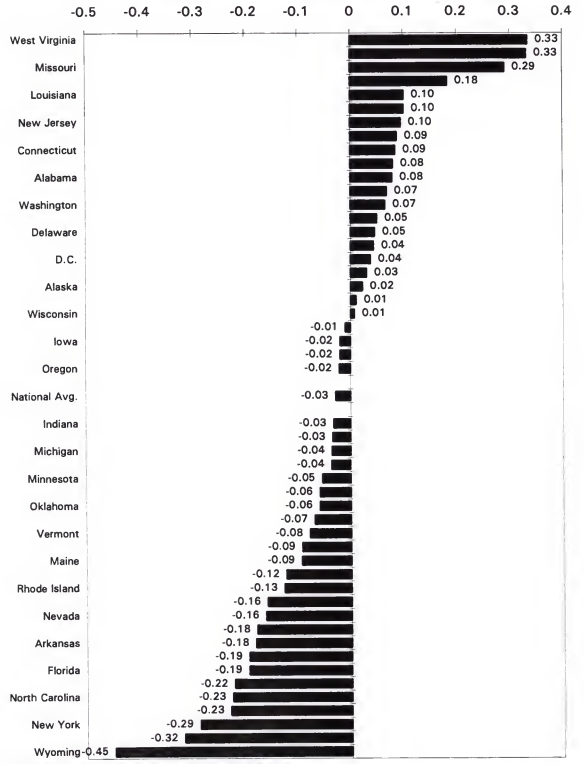
SOURCE: Compiled by the PRIME Institute University of Minnesota from data found in *Pharmaceutical Benefits Under State Medical Assistance Programs*, National Pharmaceutical Council, 1976 to 1994.

Figure 7.
Medicaid Drug Rebates: Cumulative Amount Accrued, Collected, and Uncollected 1991 to 1993



SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in Report to Congress: Medicaid Drug Rebate Program, 1992, 1993, and 1995 and HCFA estimates.

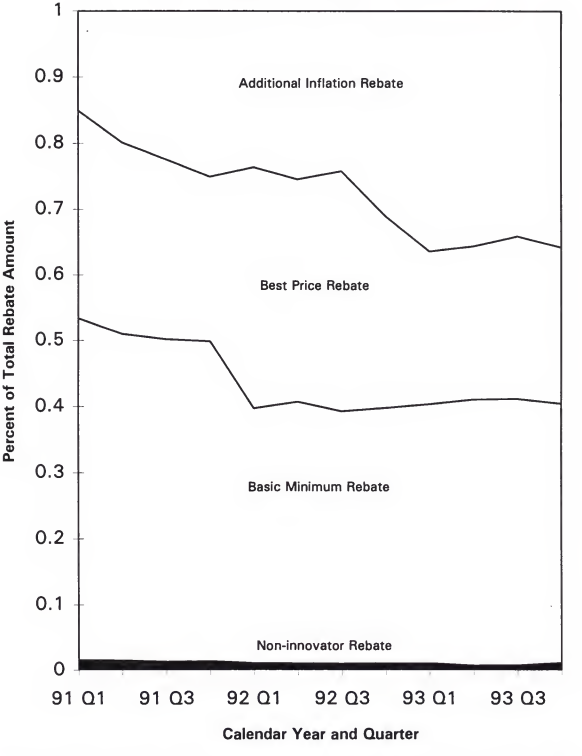
Figure 8. Percent Change in Annual Drug Expenditures per Recipient: 1990 vs. 1992



Note: Data are presented after rebates and inflation adjustment.

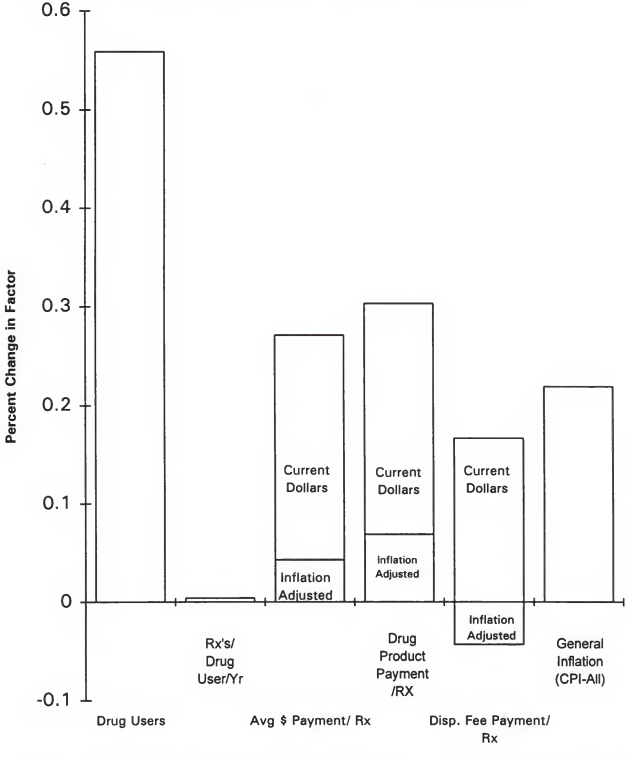
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA: National Pharmaceutical Council, 1988 to 1993); in 1990 constant dollars.

Figure 9. Medicaid Drug Rebates: Percent Distribution by Type of Rebate 1991 to 1993



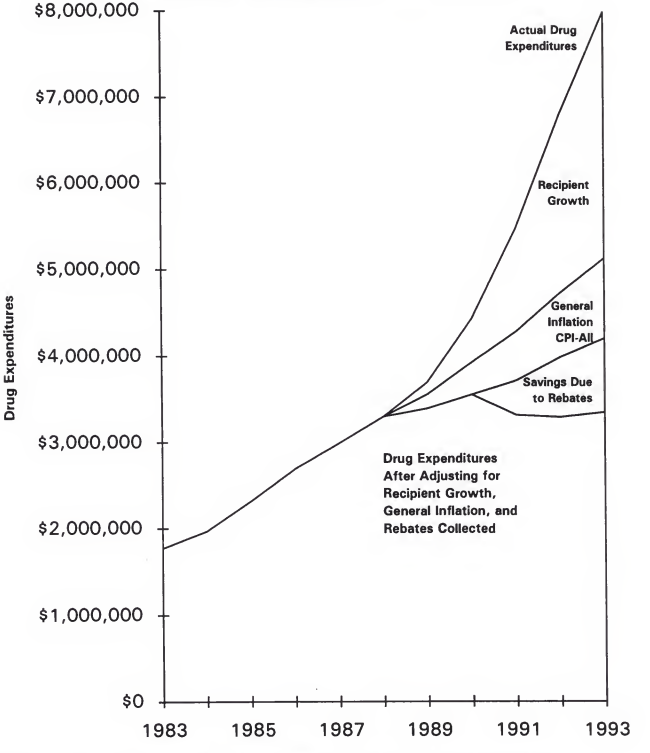
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in Report to Congress: Medicaid Drug Rebate Program, 1992, 1993, and 1995 and HCFA estimates.

Figure 10. Change in Factors Contributing to Growth in Medicaid Drug Expenditures Net of Rebates: 1988 to 1993



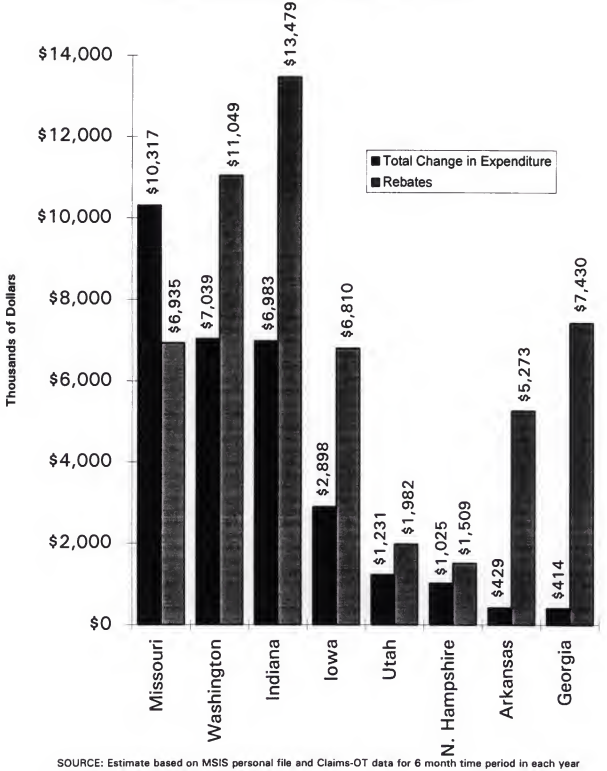
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, VA, National Pharmaceutical Council, 1988 to 1994).

Figure 11. Medicaid Drug Expenditures After Adjusting for Recipient Growth, General Inflation, and Rebates: 1983 to 1993



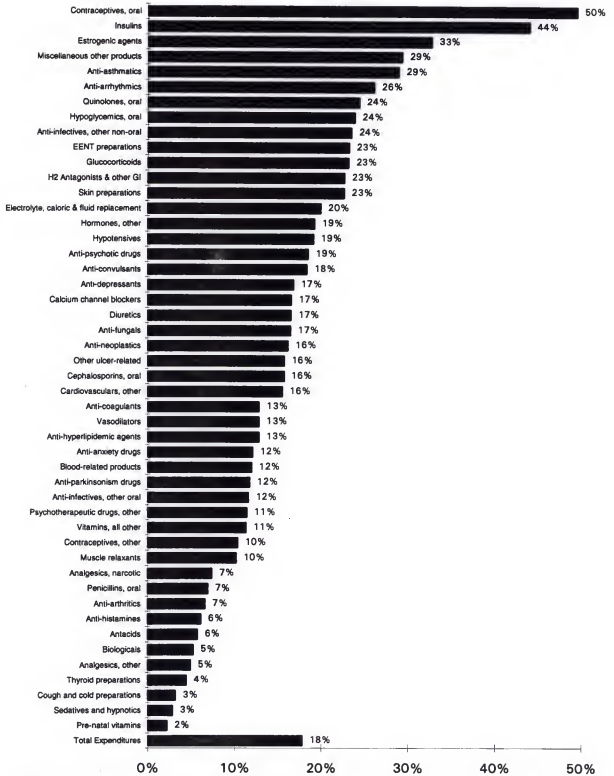
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in Pharmaceutical Benefits Under State Medical Assistance Programs, (Reston, VA: National Pharmaceutical Council, annual reports 1975 to 1994).

Figure 12.
Change in Medicaid Drug Expenditures and Rebate Payments: 1990 and 1992



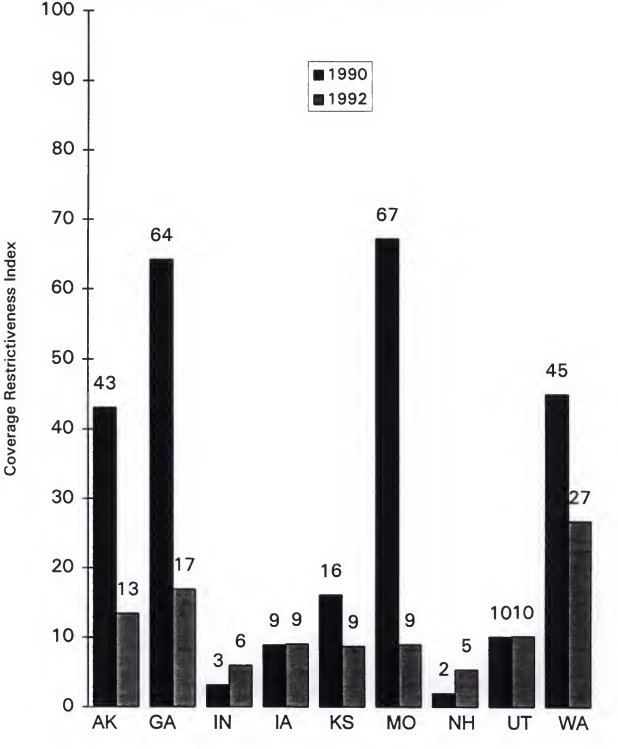
SOURCE: Estimate based on MSIS personal file and Claims-OT data for 6 month time period in each year extrapolated to one year expenditure level.

Figure 13.
Arkansas 1992: Rebate Amount as a Percent of Total Expenditures:



SOURCE: Estimate based on MSIS personal file and Claims-OT data for 6 month time period in each year extrapolated to one year expenditure level.

Figure 14.
Medicaid Coverage Restrictiveness Index from 1990 to 1992 for Selected States: All NDCs Adjusted for OBRA 90 Exclusions



* A score of 1 indicates all drugs (NDCs) covered and a score of 100 indicates no drugs (NDCs) covered.

TABLE 1.a Trends in Medicaid Drug Expenditures & Recipients: 1975 to 1993

Current Year $

Year	Total Medical Payments*	Total Drug Payments*	Drug Exp. as % of Total Medical Expend.	Total Recipients*	Drug Recipients*	Drug Recipients as % of Total Recipients	Total Medical Expend. per Total Recipient
1975	$12,242,000,000	$815,000,000	6.7%	22,007,000	14,155,000	64.3%	$556.28
1976	$14,091,000,000	$940,000,000	6.7%	22,815,000	14,883,000	65.2%	$617.62
1977	$16,239,000,000	$1,018,000,000	6.3%	22,832,000	15,370,000	67.3%	$711.24
1978	$17,992,000,000	$1,082,000,000	6.0%	21,965,000	15,188,000	69.1%	$819.12
1979	$20,472,000,000	$1,196,000,000	5.8%	21,520,000	14,283,000	66.4%	$951.30
1980	$23,311,000,000	$1,318,000,000	5.7%	21,605,000	13,707,000	63.4%	$1,078.96
1981	$27,204,000,000	$1,535,000,000	5.6%	21,980,000	14,256,000	64.9%	$1,237.67
1982	$29,399,000,000	$1,599,000,000	5.4%	21,603,000	13,547,000	62.7%	$1,360.88
1983	$32,391,000,000	$1,771,000,000	5.5%	21,544,000	13,732,000	63.7%	$1,503.48
1984	$33,891,000,000	$1,968,000,000	5.8%	21,607,000	13,935,000	64.5%	$1,568.52
1985	$37,508,000,000	$2,315,000,000	6.2%	21,814,000	13,921,000	63.8%	$1,719.45
1986	$41,005,000,000	$2,692,000,000	6.6%	22,515,000	14,704,000	65.3%	$1,821.23
1987	$45,050,000,000	$2,988,000,000	6.6%	23,109,000	15,083,000	65.3%	$1,949.46
1988	$48,710,000,000	$3,294,000,000	6.8%	22,907,000	15,323,000	66.9%	$2,126.42
1989	$54,500,000,000	$3,689,000,000	6.8%	23,511,000	15,916,000	67.7%	$2,318.06
1990	$64,859,000,000	$4,420,000,000	6.8%	25,255,000	17,294,000	68.5%	$2,568.16
1991	$76,964,000,000	$5,424,000,000	7.0%	27,967,000	19,581,000	70.0%	$2,751.96
1992	$91,316,726,920	$6,789,576,805	7.4%	30,251,378	22,062,844	72.9%	$3,018.60
1993	$101,546,607,318	$7,969,202,980	7.8%	32,668,833	23,895,611	73.1%	$3,108.36

Annual Percent Change

Year	Total Medical Payments	Total Drug Payments	Drug Exp. as % of Total Medical Expend.	Total Recipients	Drug Recipients	Drug Recipients as % of Total Recipients	Total Medical Expend. per Total Recipient
1975							
1976	15.1%	15.3%	0.2%	3.7%	5.1%	1.4%	11.0%
1977	15.2%	8.3%	-6.0%	0.1%	3.3%	3.2%	15.2%
1978	10.8%	6.3%	-4.1%	-3.8%	-1.2%	2.7%	15.2%
1979	13.8%	10.5%	-2.9%	-2.0%	-6.0%	-4.0%	16.1%
1980	13.9%	10.2%	-3.2%	0.4%	-4.0%	-4.4%	13.4%
1981	16.7%	16.5%	-0.2%	1.7%	4.0%	2.2%	14.7%
1982	8.1%	4.2%	-3.6%	-1.7%	-5.0%	-3.3%	10.0%
1983	10.2%	10.8%	0.5%	-0.3%	1.4%	1.6%	10.5%
1984	4.6%	11.1%	6.2%	0.3%	1.5%	1.2%	4.3%
1985	10.7%	17.6%	6.3%	1.0%	-0.1%	-1.0%	9.6%
1986	9.3%	16.3%	6.4%	3.2%	5.6%	2.3%	5.9%
1987	9.9%	11.0%	1.0%	2.6%	2.6%	-0.1%	7.0%
1988	8.1%	10.2%	2.0%	-0.9%	1.6%	2.5%	9.1%
1989	11.9%	12.0%	0.1%	2.6%	3.9%	1.2%	9.0%
1990	19.0%	19.8%	0.7%	7.4%	8.7%	1.2%	10.8%
1991	18.7%	22.7%	3.4%	10.7%	13.2%	2.2%	7.2%
1992	18.6%	25.2%	5.5%	8.2%	12.7%	4.2%	9.7%
1993	11.2%	17.4%	5.5%	8.0%	8.3%	0.3%	3.0%

* Raw data from sources cited. Other information is derived from these variables.

SOURCE: Compiled by PRIME Institute, University of Minnesota from HCFA 2082 data found in Pharmaceutical Benefits Under State Medical Assistance, (Reston, VA: National Pharmaceutical Council, annual volumes), Medicaid Source Book (U.S., GPO, 1993), and P. Pine, et. al., Health Care Financing Review, 1992 Annual Supplement, pp.235-269.

TABLE 1.b Trends in Medicaid Drug Use Intensity and Efficiency: 1975 to 1993

Current Year $

Year	# of Rx's Dispensed (est.)	Drug Expend. per Total Recipient	Drug Expend. per Drug Recipient	# of Rx's per Total Recipient	# of Rx's per Drug Recipient	Avg. Rx Payment (wt. avg.)*	Drug Product Payment per Rx
1975	175,660,952	$37.03	$57.58	7.98	12.41	$4.64	$4.64
1976	185,090,840	$41.20	$63.16	8.11	12.44	$5.08	$5.08
1977	186,147,204	$44.59	$66.23	8.15	12.11	$5.47	$5.47
1978	183,925,820	$49.26	$71.24	8.37	12.11	$5.88	$5.88
1979	185,996,700	$55.58	$83.74	8.64	13.02	$6.43	$6.43
1980	187,197,348	$61.00	$96.16	8.66	13.66	$7.04	$7.04
1981	194,542,046	$69.84	$107.67	8.85	13.65	$7.89	$7.89
1982	179,486,857	$74.02	$118.03	8.31	13.25	$8.91	$8.91
1983	178,403,792	$82.20	$128.97	8.28	12.99	$9.93	$9.93
1984	180,238,235	$91.08	$141.23	8.34	12.93	$10.92	$10.92
1985	192,796,027	$106.12	$166.30	8.84	13.85	$12.01	$12.01
1986	205,541,334	$119.56	$183.08	9.13	13.98	$13.10	$13.10
1987	214,944,640	$129.30	$198.10	9.30	14.25	$13.90	$13.90
1988	222,750,665	$143.80	$214.97	9.72	14.54	$14.79	$14.79
1989	224,844,340	$156.91	$231.78	9.56	14.13	$16.41	$16.41
1990	249,509,686	$175.01	$255.58	9.88	14.43	$17.71	$17.71
1991	281,368,054	$193.94	$277.00	10.06	14.37	$19.28	$19.28
1992	317,822,574	$224.44	$307.74	10.51	14.41	$21.36	$21.36
1993	348,806,969	$243.94	$333.50	10.68	14.60	$22.85	$22.85

Annual Percent Change

Year	# of Rx's Dispensed (est.)	Drug Expend. per Total Recipient	Drug Expend. per Drug Recipient	# of Rx's per Total Recipient	# of Rx's per Drug Recipient	Avg. Rx Payment (wt. avg.)	Drug Product Payment per Rx
1975							
1976	5.4%	11.3%	9.7%	1.6%	0.2%	9.5%	9.5%
1977	0.6%	8.2%	4.9%	0.5%	-2.6%	7.7%	7.7%
1978	-1.2%	10.5%	7.6%	2.7%	0.0%	7.6%	7.6%
1979	1.1%	12.8%	17.5%	3.2%	7.5%	9.3%	9.3%
1980	0.6%	9.8%	14.8%	0.2%	4.9%	9.5%	9.5%
1981	3.9%	14.5%	12.0%	2.2%	-0.1%	12.1%	12.1%
1982	-7.7%	6.0%	9.6%	-6.1%	-2.9%	12.9%	12.9%
1983	-0.6%	11.1%	9.3%	-0.3%	-1.9%	11.4%	11.4%
1984	1.0%	10.8%	9.5%	0.7%	-0.4%	10.0%	10.0%
1985	7.0%	16.5%	17.8%	6.0%	7.1%	10.0%	10.0%
1986	6.6%	12.7%	10.1%	3.3%	0.9%	9.1%	9.1%
1987	4.6%	8.1%	8.2%	1.9%	1.9%	6.1%	6.1%
1988	3.6%	11.2%	8.5%	4.5%	2.0%	6.4%	6.4%
1989	0.9%	9.1%	7.8%	-1.7%	-2.8%	10.9%	10.9%
1990	11.0%	11.5%	10.3%	3.3%	2.1%	8.0%	8.0%
1991	12.8%	10.8%	8.4%	1.8%	-0.4%	8.8%	8.8%
1992	13.0%	15.7%	11.1%	4.4%	0.2%	10.8%	10.8%
1993	9.7%	8.7%	8.4%	1.6%	1.3%	6.9%	6.9%

* Raw data from sources cited. Other information is derived from these variables.

SOURCE: Compiled by PRIME Institute, University of Minnesota from HCFA 2082 data found in Pharmaceutical Benefits Under State Medical Assistance, (Reston, VA: National Pharmaceutical Council, annual volumes), Medicaid Source Book (U.S., GPO, 1993), and P. Pine, et. al., Health Care Financing Review, 1992 Annual Supplement, pp.235-269.

TABLE 1.c Trends in Medicaid Drug Expenditures & Rebates: 1975 to 1993

Current Year $

Year	Medicaid Rebate Payments Collected (Total $)*	Total Drug Expend. After Rebates	Rebate Amount per Rx ($/Rx)	Avg. Rx Payment After Rebates	Drug Product Payment per Rx After Rebates	Drug Prod Payment as % of Rx $ After Rebates	Drug Expend. per Drug Recip. After Rebates
1975	$0	$815,000,000	$0.00	$4.64	$4.64	100.0%	$57.58
1976	$0	$940,000,000	$0.00	$5.08	$5.08	100.0%	$63.16
1977	$0	$1,018,000,000	$0.00	$5.47	$5.47	100.0%	$66.23
1978	$0	$1,082,000,000	$0.00	$5.88	$5.88	100.0%	$71.24
1979	$0	$1,196,000,000	$0.00	$6.43	$6.43	100.0%	$83.74
1980	$0	$1,318,000,000	$0.00	$7.04	$7.04	100.0%	$96.16
1981	$0	$1,535,000,000	$0.00	$7.89	$7.89	100.0%	$107.67
1982	$0	$1,599,000,000	$0.00	$8.91	$8.91	100.0%	$118.03
1983	$0	$1,771,000,000	$0.00	$9.93	$9.93	100.0%	$128.97
1984	$0	$1,968,000,000	$0.00	$10.92	$10.92	100.0%	$141.23
1985	$0	$2,315,000,000	$0.00	$12.01	$12.01	100.0%	$166.30
1986	$0	$2,692,000,000	$0.00	$13.10	$13.10	100.0%	$183.08
1987	$0	$2,988,000,000	$0.00	$13.90	$13.90	100.0%	$198.10
1988	$0	$3,294,000,000	$0.00	$14.79	$14.79	100.0%	$214.97
1989	$0	$3,689,000,000	$0.00	$16.41	$16.41	100.0%	$231.78
1990	$0	$4,420,000,000	$0.00	$17.71	$17.71	100.0%	$255.58
1991	$110,943,811	$5,313,056,189	$0.39	$18.88	$18.88	100.0%	$271.34
1992	$900,252,297	$5,889,324,508	$2.83	$18.53	$18.53	100.0%	$266.93
1993	$1,413,070,407	$6,556,132,573	$4.05	$18.80	$18.80	100.0%	$274.37

Annual Percent Change

Year	Medicaid Rebate Payments (Total $)	Total Drug Expend. After Rebates	Rebate Amount per Rx ($/Rx)	Avg. Rx Payment After Rebates	Drug Product Payment per Rx After Rebates	Drug Prod Payment as % of Rx $ After Rebates	Drug Expend. per Drug Recip. After Rebates
1975							
1976		15.3%		9.5%	9.5%	0.0%	9.7%
1977		8.3%		7.7%	7.7%	0.0%	4.9%
1978		6.3%		7.6%	7.6%	0.0%	7.6%
1979		10.5%		9.3%	9.3%	0.0%	17.5%
1980		10.2%		9.5%	9.5%	0.0%	14.8%
1981		16.5%		12.1%	12.1%	0.0%	12.0%
1982		4.2%		12.9%	12.9%	0.0%	9.6%
1983		10.8%		11.4%	11.4%	0.0%	9.3%
1984		11.1%		10.0%	10.0%	0.0%	9.5%
1985		17.6%		10.0%	10.0%	0.0%	17.8%
1986		16.3%		9.1%	9.1%	0.0%	10.1%
1987		11.0%		6.1%	6.1%	0.0%	8.2%
1988		10.2%		6.4%	6.4%	0.0%	8.5%
1989		12.0%		10.9%	10.9%	0.0%	7.8%
1990		19.8%		8.0%	8.0%	0.0%	10.3%
1991		20.2%		6.6%	6.6%	0.0%	6.2%
1992	711.4%	10.8%	618.4%	-1.9%	-1.9%	0.0%	-1.6%
1993	57.0%	11.3%	43.0%	1.4%	1.4%	0.0%	2.8%

* Raw data from sources cited. Other information is derived from these variables.

SOURCE: Compiled by PRIME Institute, University of Minnesota from HCFA 2082 data found in Pharmaceutical Benefits Under State Medical Assistance, (Reston, VA: National Pharmaceutical Council, annual volumes), Medicaid Source Book (U.S., GPO, 1993), and P. Pine, et. al., Health Care Financing Review, 1992 Annual Supplement, pp.235-269.

Table 2 Medicaid Rebates Accrued and Collected: 1991 to 1993

FY-Qtr	CY-Qtr	# of States Reporting	Rebate Accrued (1)	Rebate Collected (2)	Cumulative Rebate Accrued	Cumulative Rebate Collected	Cumulative Rebate Uncollected
91 Q2	91 Q1		$99,618,948	$4,323,329	$99,618,948	$4,323,329	$95,295,619
91 Q3	91 Q2		$151,312,486	$6,763,614	$250,931,434	$11,086,943	$239,844,491
91 Q4	91 Q3	39	$191,328,922	$99,856,868	$442,260,356	$110,943,811	$331,316,545
92 Q1	91 Q4	42	$170,092,916	$140,087,874	$612,353,272	$251,031,685	$361,321,587
92 Q2	92 Q1	50	$242,742,879	$204,114,349	$855,096,151	$455,146,034	$399,950,117
92 Q3	92 Q2	50	$202,402,012	$261,584,604	$1,057,498,163	$716,730,638	$340,767,525
92 Q4	92 Q3	50	$294,465,470	$1,261,496,246	$1,011,196,108	$250,300,138	
93 Q1	92 Q4	50	$274,000,000	$343,306,924	$1,535,496,246	$1,354,503,032	$180,993,214
93 Q2	93 Q1	50	$280,000,000	$292,145,269	$1,815,496,246	$1,646,648,301	$168,847,945
93 Q3	93 Q2	50	$258,000,000	$429,890,937	$2,073,496,246	$2,076,539,238	($3,042,992)
93 Q4	93 Q3	50	$255,000,000	$347,727,277	$2,328,496,246	$2,424,266,515	($95,770,269)
94 Q1	93 Q4	49	$257,000,000	$410,656,647	$2,585,496,246	$2,834,923,162	($249,426,916)
	CY 91		$612,353,272	$251,031,685	$612,353,272	$251,031,685	$1,027,778,242
	CY 92		$923,142,974	$1,103,471,347	$1,535,496,246	$1,354,503,032	$1,172,010,994
	CY 93		$1,050,000,000	$1,480,420,130	$2,585,496,246	$2,834,923,162	($179,392,233)
FY 91			$442,260,356	$110,943,811	$442,260,356	$110,943,811	$666,456,655
FY 92			$819,235,890	$900,252,297	$1,261,496,246	$1,011,196,108	$1,352,339,367
FY 93			$1,067,000,000	$1,413,070,407	$2,328,496,246	$2,424,266,515	$251,027,897

FY-Qtr	CY-Qtr	# of States Reporting	Total Prescribed Drugs Payments (2)	Rebates Accrued as % of Drug Payments	Rebates Collected as % of Drug Payments	Rebates Uncollected as % of Drug Payments	Rebates Collected as % Rebates Accrued
91 Q2	91 Q1		$532,449,877	18.7%	0.8%	17.9%	4.3%
91 Q3	91 Q2		$539,773,049	28.0%	1.3%	44.4%	4.5%
91 Q4	91 Q3	39	$1,316,433,341	14.5%	7.6%	25.2%	52.2%
92 Q1	91 Q4	42	$1,506,553,180	11.3%	9.3%	24.0%	82.4%
92 Q2	92 Q1	50	$1,769,379,913	13.7%	11.5%	22.6%	84.1%
92 Q3	92 Q2	50	$1,807,179,800	11.2%	14.5%	18.9%	129.2%
92 Q4	92 Q3	50	$1,868,567,330	10.9%	15.8%	13.4%	144.3%
93 Q1	92 Q4	50	$1,932,957,927	14.2%	17.8%	9.4%	125.3%
93 Q2	93 Q1	50	$2,081,453,512	13.5%	14.0%	8.1%	104.3%
93 Q3	93 Q2	50	$2,115,901,074	12.2%	20.3%	-0.1%	166.6%
93 Q4	93 Q3	50	$2,188,556,768	11.7%	15.9%	-4.4%	136.4%
94 Q1	93 Q4	49	$2,191,129,198	11.7%	18.7%	-11.4%	159.8%
	CY 91		$3,895,209,447	15.7%	6.4%	26.4%	41.0%
	CY 92		$7,378,084,970	12.5%	15.0%	15.9%	119.5%
	CY 93		$8,577,040,552	12.2%	17.3%	-2.1%	141.0%
FY 91			$2,388,656,267	18.5%	4.6%	27.9%	25.1%
FY 92			$6,951,680,223	11.8%	13.0%	19.5%	109.9%
FY 93			$8,318,869,281	12.8%	17.0%	3.0%	132.4%

SOURCES:

(1) HCFA estimates.

(2) Report to Congress: Medicaid Drug Rebate Program, 1992, 1993, & 1995.

Table 3. Medicaid Rebates: Distribution by Type in 1991 to 1993

FY-Qtr	CY-Qtr	Total Rebate Amount	Basic Rebate Amount w/o Best Price or Add'l Rebate	Best Price Contribution to Rebate Amount	Additional (Inflation) Rebate Amount	Non-Innovator Drug Rebate Amount
		Rebate Amounts Accrued (1)				
91 Q2	91 Q1	$99,618,948	$51,584,275	$31,462,548	$15,009,946	$1,562,179
91 Q3	91 Q2	$151,312,486	$74,819,663	$44,122,132	$30,031,484	$2,339,207
91 Q4	91 Q3	$191,328,922	$93,450,542	$52,410,452	$42,903,189	$2,564,740
92 Q1	91 Q4	$170,092,916	$82,444,281	$42,611,553	$42,644,563	$2,392,520
92 Q2	92 Q1	$242,742,879	$93,800,204	$88,907,755	$57,335,216	$2,699,704
92 Q3	92 Q2	$202,402,012	$80,203,996	$68,463,028	$51,526,183	$2,208,805
92 Q4	92 Q3	$203,998,082	$78,044,643	$74,405,685	$49,427,497	$2,120,257
93 Q1	92 Q4	$274,000,000	$106,000,000	$80,000,000	$85,000,000	$3,000,000
93 Q2	93 Q1	$280,000,000	$110,000,000	$65,000,000	$102,000,000	$3,000,000
93 Q3	93 Q2	$258,000,000	$104,000,000	$60,000,000	$92,000,000	$2,000,000
93 Q4	93 Q3	$255,000,000	$103,000,000	$63,000,000	$87,000,000	$2,000,000
94 Q1	93 Q4	$257,000,000	$101,000,000	$61,000,000	$92,000,000	$3,000,000
	CY 91	$612,353,272	$302,298,762	$170,606,684	$130,589,181	$8,858,645
	CY 92	$923,142,974	$358,048,843	$311,776,467	$243,288,897	$10,028,766
	CY 93	$1,050,000,000	$418,000,000	$249,000,000	$373,000,000	$10,000,000
FY 91		$442,260,356	$219,854,480	$127,995,131	$87,944,619	$6,466,126
FY 92		$819,235,890	$334,493,125	$274,388,020	$200,933,459	$9,421,285
FY 93		$1,067,000,000	$423,000,000	$268,000,000	$366,000,000	$10,000,000
		Rebate Amount Accrued by Type of Rebate as a % of Total Rebate Amount Accrued				
91 Q2	91 Q1	100.0%	51.8%	31.6%	15.1%	1.6%
91 Q3	91 Q2	100.0%	49.4%	29.2%	19.8%	1.5%
91 Q4	91 Q3	100.0%	48.8%	27.4%	22.4%	1.3%
92 Q1	91 Q4	100.0%	48.5%	25.1%	25.1%	1.4%
92 Q2	92 Q1	100.0%	38.6%	36.6%	23.6%	1.1%
92 Q3	92 Q2	100.0%	39.6%	33.8%	25.5%	1.1%
92 Q4	92 Q3	100.0%	38.3%	36.5%	24.2%	1.0%
93 Q1	92 Q4	100.0%	38.7%	29.2%	31.0%	1.1%
93 Q2	93 Q1	100.0%	39.3%	23.2%	36.4%	1.1%
93 Q3	93 Q2	100.0%	40.3%	23.3%	35.7%	0.8%
93 Q4	93 Q3	100.0%	40.4%	24.7%	34.1%	0.8%
94 Q1	93 Q4	100.0%	39.3%	23.7%	35.8%	1.2%
	CY 91	100.0%	49.4%	27.9%	21.3%	1.4%
	CY 92	100.0%	38.8%	33.8%	26.4%	1.1%
	CY 93	100.0%	39.8%	23.7%	35.5%	1.0%
FY 91		100.0%	49.7%	28.9%	19.9%	1.5%
FY 92		100.0%	40.8%	33.5%	24.5%	1.2%
FY 93		100.0%	39.6%	25.1%	34.3%	0.9%

SOURCES:

(1) HCFA estimates.

(2) Report to Congress: Medicaid Drug Rebate Program, 1992, 1993, & 1995.

Table 4.
Relationship of Rebate Payments to Changes in Expenditures from Shifts in Utilization Adjusted for Enrollment Changes (in $ 1,000s)

	Arkansas	Georgia	Iowa	Indiana	Missouri	New Hamp.	Utah	Washington
I. Change in Expenditure Due to (a):								
a. New Drugs (b)	$1,063.7	$1,374.7	$1,043.3	$2,274.5	$1,527.3	$166.8	$381.9	$2,034.8
b. Substitution of existing NDCs (c)	$1,909.7	$1,011.5	$1,340.7	$2,659.2	$4,304.2	$512.2	$475.9	$2,923.3
c. Utilization of old NDCs	($2,544.70)	($1,972.30)	$514.2	$2,049.4	$4,485.2	$346.3	$373.3	$2,080.9
d. Total change in utilization	$428.5	$413.9	$2,898.2	$6,983.1	$10,316.7	$1,035.3	$1,231.1	$7,039.0
e. Rebate payment	$5,272.6	$7,429.7	$6,809.6	$13,478.9	$6,934.7	$1,508.8	$1,982.3	$11,049.0
II. Benefit Ratios								
a. Rebates/total change in utilization	12.30	17.95	2.35	1.93	0.67	1.47	1.61	1.57
b. Rebates/Total change in utilization net new drugs	(d)	(d)	3.67	2.86	0.79	1.76	2.33	2.21

SOURCE: Appendix Table 6

NOTES:

(a) All Figures adjusted by calculating 1992 expenditures with 1990 enrollments.

(b) New drugs are those NCDs whose combination of drug entity, dosage form and strength did not exist in 1990

(c) Substitution of NDCs is the net amount from subtracting expenditures on NDCs used only in 1990 form the sum of expenditures for NDCs that existed in 1990, but were not prescribed in a state plus expenditures for new NDCs for existing drugs

(d) Ratios would be based on negative changes in utilization expenditures

Table 5.
Decomposition of Changes in Drug Expenditures: 1990 vs. 1992

State	Total Drug Expend.	Drug Expend. Net of Rebates	Drug Product Prices	Drug Users per 1,000 Enrollees	Rx's per User	Changes in Enrollment Mix
Total for All Eligibles						
Arkansas	9.4%	-10.2%	11.3%	-12.7%	-2.7%	15.4%
Georgia	27.0%	1.2%	12.7%	-8.9%	-2.0%	23.3%
Iowa	34.8%	7.7%	21.4%	-0.3%	4.1%	12.2%
Indiana	56.6%	23.9%	16.4%	1.1%	4.4%	29.2%
Missouri	72.3%	35.7%	12.3%	21.5%	9.5%	15.1%
N. Hampshire	63.7%	29.0%	14.4%	1.7%	3.2%	36.6%
Utah	58.3%	23.9%	15.9%	4.7%	-1.3%	27.8%
Washington	51.1%	17.0%	15.9%	1.1%	0.0%	26.0%

Note: Independent factors will not sum across to equal total expenditure changes, due to cross-product terms

Table 6
Decomposition of Changes in Drug Expenditures: By Basis of Eligibility 1990 vs. 1992

State	Total Drug Expend.	Drug Expend. Net of Rebates	Drug Product Prices	Drug Users per 1,000 Enrollees	Rx's per User	Changes in Enrollment Mix
Aged Eligibles						
Arkansas	3.9%	-14.9%	11.4%	-12.0%	-1.0%	5.5%
Georgia	13.3%	-9.5%	11.7%	-10.8%	-3.0%	10.0%
Iowa	27.2%	2.9%	27.6%	-2.9%	3.5%	8.3%
Indiana	37.7%	10.0%	15.9%	-0.9%	6.3%	14.2%
Missouri	59.5%	26.8%	12.6%	19.6%	10.4%	8.0%
N. Hampshire	48.4%	18.7%	13.9%	9.3%	3.6%	12.8%
Utah	33.8%	4.7%	15.9%	0.2%	-1.3%	11.4%
Washington	34.2%	4.2%	17.2%	-1.1%	1.2%	11.0%
Blind/Disabled						
Arkansas	12.8%	-8.3%	11.4%	-17.6%	-5.1%	26.0%
Georgia	26.5%	0.1%	14.3%	-9.1%	-1.8%	22.6%
Iowa	42.2%	13.0%	18.4%	-0.1%	3.7%	18.0%
Indiana	56.3%	22.8%	17.7%	0.8%	1.3%	26.5%
Missouri	88.9%	48.5%	12.0%	26.9%	9.1%	21.7%
N. Hampshire	61.7%	26.1%	15.5%	-10.1%	5.5%	47.1%
Utah	58.8%	24.1%	17.6%	1.2%	-2.7%	32.0%
Washington	63.1%	25.8%	15.3%	0.8%	-0.3%	36.0%
AFDC/Poverty Adults						
Arkansas	0.3%	-17.5%	7.7%	-22.1%	-5.9%	20.4%
Georgia	29.6%	2.3%	10.4%	-20.8%	-4.3%	46.6%
Iowa	30.3%	-0.3%	12.5%	2.1%	3.3%	7.7%
Indiana	73.4%	34.4%	14.3%	-3.6%	1.9%	48.2%
Missouri	70.5%	28.4%	10.8%	20.8%	7.5%	13.0%
N. Hampshire	114.8%	62.7%	12.6%	-3.4%	-2.8%	85.7%
Utah	61.9%	24.0%	12.8%	6.0%	2.0%	26.8%
Washington	68.7%	35.4%	16.0%	10.5%	-1.4%	33.7%
AFDC/Poverty Children						
Arkansas	37.0%	17.2%	13.0%	1.2%	-4.3%	28.2%
Georgia	88.0%	51.6%	14.7%	11.1%	-2.0%	49.9%
Iowa	47.7%	19.2%	15.6%	7.0%	1.8%	16.7%
Indiana	129.7%	83.5%	17.0%	19.1%	3.6%	63.9%
Missouri	84.3%	45.8%	12.7%	9.1%	6.7%	29.6%
N. Hampshire	121.2%	76.0%	14.5%	12.2%	-4.8%	73.5%
Utah	97.4%	58.9%	15.6%	21.6%	-4.7%	43.7%
Washington	68.7%	35.4%	16.0%	10.5%	-1.4%	33.7%

Note: Independent factors will not sum across to equal total expenditure changes, due to cross-product terms

Table 7.
Restrictiveness Index for Medicaid: 1990 & 1992
All NDCs Adjusted for OBRA 90 Exlcusions

	SS # of NDC's	IMS # of NDC's	NMS # of NDC's	OTC # of NDC's	Total # of NDC's (unweighted)	SS+IMS # of NDC's (weighted average indices)	Rx # of NDC's	Total # of NDC's
1990								
Formulary Restrictiveness Index (FRI= 1+(1-% NDCs reimbursed))								
Arkansas	49	25	19	75	37	46	40	43
Georgia	60	66	58	99	71	61	60	64
Indiana	2	3	5	7	6	2	3	3
Iowa	2	2	5	68	24	2	2	9
Kansas	22	5	5	11	8	20	17	16
Missouri	73	53	44	92	60	70	65	67
New Hampshire	2	1	3	1	2	2	2	2
Utah	2	3	6	75	26	2	3	10
Washington	49	30	25	77	42	46	42	45
1992								
Formulary Restrictiveness Index (FRI= 1+(1-% NDCs reimbursed))								
Arkansas	11	3	3	57	24	10	9	13
Georgia	14	7	5	66	28	13	11	17
Indiana	6	0	0	23	9	5	4	6
Iowa	6	-1	-1	56	21	5	4	9
Kansas	9	0	-1	32	12	8	6	9
Missouri	10	1	0	27	11	9	7	9
New Hampshire	6	-1	-1	20	7	5	4	5
Utah	7	0	0	56	21	6	5	10
Washington	30	15	10	50	27	28	24	27
OBRA 90 adjustment	30	30	30	30	30	30	30	30
Change in Formulary Restrictiveness Index (1992 - 1990)								
Arkansas	-38	-21	-15	-18	-14	-35	-31	-30
Georgia	-46	-58	-53	-34	-43	-48	-49	-47
Indiana	4	-3	-6	15	3	3	1	3
Iowa	5	-3	-5	-12	-3	3	2	0
Kansas	-13	-5	-6	22	5	-12	-11	-7
Missouri	-63	-52	-44	-65	-49	-61	-58	-58
New Hampshire	4	-2	-4	19	5	3	2	3
Utah	6	-3	-6	-19	-5	4	2	0
Washington	-19	-14	-15	-27	-15	-18	-17	-18